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ELECTRONIC PRESCRIBING OF CONTROLLED SUBSTANCES: ADDRESSING HEALTH CARE AND LAW ENFORCEMENT PRIORITIES

HEARING

BEFORE THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

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ELECTRONIC PRESCRIBING OF CONTROLLED SUBSTANCES: ADDRESSING HEALTH CARE AND LAW ENFORCEMENT PRIORITIES

TUESDAY, DECEMBER 4, 2007

U.S. SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, DC

The Committee met, pursuant to notice, at 10 a.m., in room 226, Dirksen Senate Office Building, Hon. Sheldon Whitehouse, presiding.

Present: Senators Kennedy, Specter, and Coburn.

OPENING STATEMENT OF HON. SHELDON WHITEHOUSE, A U.S. SENATOR FROM THE STATE OF RHODE ISLAND

Senator WHITEHOUSE. Welcome, everyone. I will call this hearing of the Judiciary Committee to order.

We are here today to discuss an issue that is, as many issues are, at the conjunction of different departments and different responsibilities here in the government, and that is the electronic prescription of controlled substances.

I am Sheldon Whitehouse, a member of this committee, and I have the honor to chair this particular hearing. I am joined by my very distinguished colleague from Massachusetts, Senator Kennedy, and I am very thrilled that he is here today. I appreciate it.

Senator, with your permission I'll make a brief opening statement and then turn to you for opening remarks, then we can go on to the witnesses.

And the Ranking Member has arrived, Senator Specter of Pennsylvania.

Senator SPECTER. I arrived promptly at 10, may the record show. [Laughter.]

Senator WHITEHOUSE. The committee today will consider the question of electronic prescription of controlled substances. Viewed up close, this issue involves technical questions about competing information technology systems, the evidentiary needs of law enforcement officials, and the prevention of drug addiction in America. But it also puts at issue our struggle to rein in exploding health care costs. Solving this e-prescribing dilemma will help us fulfill our obligation in Congress to provide high-quality health care to all Americans at reasonable cost.

While electronic prescription is by no means the end-all, be-all of health care reform, it is an important piece of the puzzle. For starters, electronic prescription could save $20 billion per year—this is

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Washington, so this is a "b", billion dollars per year—through reduced adverse drug events, increased patient adherence to prescription regimens, and improved administrative efficiency.

It is also a logical gateway for many providers to the more comprehensive health care information technology system that we need, one that could save, by some reports, as much as $346 billion per year, and certainly would save multiple tens of billions of dollars per year.

But until doctors can prescribe electronically, they are unlikely to adopt a fully integrated electronic health record system which could decrease medical errors, better coordinate care, particularly for high-cost, chronically ill patients, and enhance efficiency throughout the system, though it is an important gateway.

Indeed, to quote Department of Health and Human Services Secretary Leavitt, "The benefits of electronic prescribing are unchallengeable. E-prescribing is not only more efficient and convenient for consumers, but widespread use would eliminate thousands of medication errors every year. E-prescribing needs faster implementation."

Unfortunately, there is one road block in our way: current law does not permit the electronic prescription of schedule drugs. A doctor can electronically prescribe medication that is not regulated by the Drug Enforcement Administration, totaling roughly 90 percent of prescriptions, but must rely on paper and pen for the remaining 10 percent. The inevitable result is that many doctors simply refuse to prescribe any medications electronically because it is too burdensome to operate two separate systems, an electronic one for regular prescriptions and a paper and pen one for controlled drugs.

Imagine if you are the doctor, prescribing both controlled and non-controlled medication to the same patient in the same visit and having to use two systems for that, and you will understand the confusion that this creates. Everyone seems to support the notion that it is time for DEA to issue regulations permitting e-prescription of controlled substances. Indeed, I understand that the Drug Enforcement Administration itself agrees with this notion.

Therefore, the only two questions that we have to explore this morning are when, and how? First, the "when". DEA issued e-prescription regulations 4 years ago, but they were roundly criticized for being too restrictive and were never implemented.

I understand the DEA has been at work on a new set of regulations since at least 2006, but has been unwilling yet to commit to any sort of timeline for completion and has not as yet circulated these draft regulations outside of DEA. At this point we could conclude the Bush administration without progress at this rate, and so I am hoping that we can accelerate things.

The "how" question is a little bit more complex. Roughly 6 million people per month, 2.5 percent of the population, use prescription medication for non-medical purpose, and this number has more than doubled in the last 15 years. I have been the Attorney General of my State, I've been a U.S. Attorney. I fully appreciate that any e-prescription must preserve the government's ability to investigate and prosecute cases where prescriptions are unlawfully

used to acquire controlled substances, known as diversion cases in law enforcement.

But protecting these law enforcement capabilities need not be incompatible with giving doctors, pharmacies, and patients the tools necessary for e-prescription. We target military weapons. We engage in billion-dollar financial transactions. We transmit national security information and we engage in countless important private communications electronically every day. I can't believe we can't figure out a way to prescribe Vicodin electronically. Indeed, as we will hear from witnesses on the second panel, those necessary tools do exist.

So, as President Bush said of our health care system just a few weeks ago—not a man I frequently quote, but here we are—"When it comes to information technology, they are light-years behind a lot of America. Perhaps the best way to describe it is that we still get doctors handwriting files." He went on to say, "Congress ought to focus on spreading information technology throughout health care."

Well, here we are today. I look forward to hearing testimony, both from DEA and the Department of Health and Human Services, on how they are working to help the President fulfill this mandate. Later this morning I look forward to hearing the perspective of doctors, pharmacists, and experts in the field of e-prescription as well.

Our Ranking Member, Senator Specter.

STATEMENT OF HON. ARLEN SPECTER, A U.S. SENATOR FROM THE STATE OF PENNSYLVANIA

Senator SPECTER. Thank you, Mr. Chairman. I note your comment that you don't often quote the President. He is widely quoted, occasionally favorably, by Democrats, but frequently quoted unfavorably by the Democrats. But I don't think he's a central party to this particular issue, and it is one of importance.

Although I cannot stay too long, and Senator Coburn will represent the Republican side during the course of the hearing, I did want to come to lend my voice in support of using e-prescriptions. We have a very distinguished array of witnesses. We have DEA here to express their point of view, and CMS to discuss their administration of the e-prescription program at HHS.

I am pleased to note the presence of Mike Podgurski, who is Vice President for Pharmacy Services for Rite-Aid, a major Pennsylvania corporation with pharmacies all over the United States, specifically, 5,000 in stores in 31 States. We thank them for their participation in this hearing.

I do believe that it is time that this issue came into the 21st century. Electronic systems are in use. Having had some experience in prosecution, I can understand DEA's interest in having a paper trail. But these electronic transmissions are trailable. Some of the most significant evidence these days is dug up on e-mails, so electronic transmission would be a great help. Since you can prescribe certain controlled substances orally, it seems to me that using an electronic prescription system is an equallly sound way to approach it.

Senator Whitehouse has already outlined the kinds of savings which are involved, and I think it would be very, very useful. So it is my hope that this hearing will shed some significant light and give the program a push, and perhaps motivate DEA to move forward on a timeline to set forth their position.

Thank you, Mr. Chairman.

Senator WHITEHOUSE. Well, I thank the distinguished Ranking Member for honoring us with his presence today. I do appreciate it very, very much.

I would recognize the senior Senator from Massachusetts, Senator Kennedy.

STATEMENT OF HON. EDWARD M. KENNEDY, A U.S. SENATOR FROM THE STATE OF MASSACHUSETTS

Senator KENNEDY. Thank you very much, Senator Whitehouse, Senator Specter. On having this hearing, I first of all want to commend Senator Whitehouse for his interest and his knowledge and awareness about this issue. As an Attorney General, he has really led the country in terms of his commitment, in terms of quality health care in the State of Rhode Island and had a particular interest in the role of information technology. We know we've had the various GAO studies that estimated about $30 billion a year could be saved in terms of adverse drug reaction with the use of information technology. Thirty billion dollars could be saved.

So, there are broad policy issues, whether the DEA is playing the constructive role in terms of making available needed narcotics for people that have the kinds of health conditions where those are necessary, and also how you're going to be able to police the fraudulent use, which is an issue and a problem in terms of the country. It's a balance. That's what this hearing is about. But it has broad implications as well.

In many respects, the way that the DEA goes will have an implication in terms of where the Nation goes on issues of information technology and the use of e-prescribing. So they have incredible, broad health kinds of implications, these decisions, and that's why this hearing is so important and why I commend Senator Whitehouse for his interest. We've lagged behind other nations in the world in terms of the use of information technology.

Just a final point. We in Massachusetts have both physicians and pharmacies that have already begun adopting e-prescribing, and our patients are benefiting. Massachusetts was recognized as the State with the highest volume of electronic prescriptions per capita in the country. We have an infrastructure to move forward with incorporating controlled substances into the electronic prescribing. It's my understanding that Massachusetts applied for a waiver from DEA to allow them to move ahead after they had spent a great deal of time in working through this issue. I'm disappointed to hear that the waiver was rejected.

So, I hope that the DEA's concerns could be addressed in a manner that would allow the health care providers, the patients, to benefit from the advantages of electronic prescribing. This is a very important health care issue. There are a lot of concerns that American families have about health care, such as access, cost, availability, dependability, reliability, a lot of different kinds of issues.

Prevention, case management. A thousand different kinds of issues. But this one here is of incredible importance and consequence.

I just commend the Chair for having it, and I hope the DEA and CMS will work very closely with the Chair and others interested in this issue so we can make progress. It's really key in terms of quality and in terms of cost, and it seems to me in terms of law enforcement, as has been the case by Senator Whitehouse with his work as Attorney General, and someone who understands this and its importance in terms of law enforcement. That's why the Judiciary Committee is having this hearing. I want to commend you and thank you for having it, and look forward to working with you and our witnesses to see if we can't make progress.

Senator WHITEHOUSE. Well, thank you, Senator Kennedy. It's a great honor for all of us to have you here. There is no person in this institution who has shown more leadership on health care than you, so we're honored that you could stop by today. I appreciate it very much.

We have as our first panel of witnesses Joseph Rannazzisi from the Drug Enforcement Administration; and Tony Trenkle, who is the Director of the Office of E-Health Standards and Services. If I might ask you gentlemen to please stand to be sworn.

[Whereupon, the witnesses were duly sworn.]

Senator WHITEHOUSE. Thank you very much. Please be seated.

I believe, at least in my order of proceeding, that Mr. Rannazzisi goes first. So if you'd care to give your opening statement now, I would appreciate it. I thank you for being here. I understand that you oversee DEA's effort to prevent, detect, and investigate the diversion of pharmaceutical controlled substances and listed chemicals, so I appreciate you taking time out of your busy work to come here. Thank you, sir.

STATEMENT OF JOSEPH T. RANNAZZISI, DEPUTY ASSISTANT ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION, OFFICE OF DIVERSION CONTROL, ALEXANDRIA, VA

Mr. RANNAZZISI. Thank you, Chairman Whitehouse. Good morning. On behalf of Acting Administrator Michele Leonhart and the men and women of the Drug Enforcement Administration, I want to thank you for this opportunity to appear today to discuss DEA's ongoing efforts to establish standards that will permit electronic prescribing for controlled substances.

Before I elaborate on our progress toward this end, I want to explain the need for ensuring the distribution system for controlled substances, even when it includes electronic prescription, remains a closed system as envisioned by the Controlled Substances Act, also known as the CSA. In recent years we've seen a remarkable reduction in the number of individuals who abuse illicit drugs. However, we are now fighting an alarming increase in the abuse and trafficking of prescription medication. In just 5 years, the number of Americans abusing prescription drugs rose more than two-thirds, from 3.8 million abusers to nearly 7 million.

DEA is charged with the responsibility to prevent diversion while ensuring there is an adequate, non-interrupted supply of pharmaceutical drugs to meet legitimate medical needs. Since passage of

the CSA, there have been significant technological advancements that affect the way DEA carries out its mission.

The information and technological revolution promotes business models that improve efficiency, shrink costs, and reduce paperwork. Unfortunately, DEA's investigative and regulatory obligations must factor in an element that is not part of such innovative business models: the criminal element. To be effective, DEA must be able to identify, collect, and preserve evidence for subsequent criminal, civil, and administrative proceedings.

An area not contemplated by Congress during the creation of the CSA was the Internet, which has drastically altered the medical community's traditional business models. As the number of Americans with Internet access has increased, so, too, have the opportunities for individuals to acquire pharmaceutical controlled substances over the Internet, both legally and illegally.

Technology, when used appropriately, can increase efficiency and reduce costs. However, DEA knows all too well that individuals are more than willing to exploit weaknesses in technology for financial gain. A small number of individuals can wreak havoc in a very short period of time.

Let me give you an example of how technology can be exploited, and the subsequent damage. In 2006 alone, just 34 pharmacies used the Internet to illegally divert more than 98 million dosage units of hydrocodone. Now, DEA recognizes that there are strong societal benefits realized by enabling individuals to fill their prescriptions over the Internet, as long as all of the parties involved do so in accordance with the law. However, the anonymity of the Internet and the proliferation of Web sites that facilitate illicit transactions for pharmaceutical controlled substances have given drug traffickers and drug abusers the means to circumvent the law, as well as sound medical practice.

The overwhelming majority of prescribing in America is conducted responsibly, but a small number of unscrupulous practitioners prescribe controlled substances improperly; carelessly at best, knowingly at worst. Their actions help supply America's second most widespread drug addiction problem.

In the case of electronic transmissions involving prescriptions for controlled substances, DEA's responsibility to identify, collect, and preserve evidence is a challenging task. According to a recent report by the Kaiser Family Foundation, there were more than 3.5 billion prescriptions written in the U.S. in 2005. The report noted that this was a 71 percent increase from the number of prescriptions written in 1994, compared to a U.S. population growth of only 9 percent during that same period. Based upon these figures, the number of prescriptions written for controlled substances in 2005 were between 360 and 400 million.

To meet statutory obligations, DEA must ensure that any electronic system used for transmitting a prescription for a controlled substance include three factors: authentication, non-repudiation, and integrity in the recordkeeping process and system. It is critical that we acknowledge and account for the clear and distinct differences between the system for non-controlled substances and one for a powerful and addictive controlled substance.

The technology and standards which are ultimately promulgated for the electronic prescribing of controlled substances cannot simply be plug-and-play; a system that does not have adequate safeguards and accountability simply provides a plausible defense for those who would exploit such a system to divert even more controlled substances to those willing to abuse them.

I'd like to close by saying that DEA is committed to establishing a system of electronic prescribing, but only a system that's in the best interests of the American public. A system without adequate safeguards is nothing more than an electronic superhighway for prescriptions, with an express lane for diversion. DEA is committed to protecting the public, first and foremost.

On behalf of the Drug Enforcement Administration, I want to thank you for this opportunity to appear today and I look forward to answering any questions you may have.

[The prepared statement of Mr. Rannazzisi appears in the appendix.]

Senator WHITEHOUSE. Thank you.

I think what I'll do right now is actually go to the opening statement of Mr. Trenkle, and then we can have a discussion back and forth with both of you.

Mr. Trenkle.

STATEMENT OF TONY TRENKLE, OFFICE OF E-HEALTH STANDARDS AND SERVICES, CENTERS FOR MEDICARE AND MEDICAID SERVICES, BALTIMORE, MD

Mr. TRENKLE. Good morning, Senator Whitehouse. I am pleased to be here today to discuss CMS's leadership role in the ongoing development of uniform standards for electronic prescribing for the Medicare Part D program.

More than 43 million people are covered by Medicare alone this year. Since the enactment of the Medicare Prescription Drug Improvement and Modernization Act of 2003, CMS has been working with its government partners and industry stakeholders to develop and implement standards that would create an infrastructure that will allow us to realize the significant potential public health and safety benefits e-prescribing offers for the Medicare population.

The MMA directed CMS to promulgate standards for a voluntary e-prescribing program in the Medicare Part D prescription drug benefit. For several years now, CMS has pursued an incremental approach to adopting final uniform standards for Part D e-prescribing that are consistent with the MMA's objectives of patient safety, quality, and efficiency.

And as you mentioned, beyond Part D, facilitating the widespread adoption of e-prescribing is one of the key action items in the administration's effort to build a nationwide interoperable electronic health information infrastructure.

The current handwritten medication prescription process, as we know, is prone to errors. In addition to ineligible prescriptions, it is estimated that some 530,000 adverse drug events take place annually among Medicare beneficiaries alone. The Institute of Medicine last year reported that more than 1.5 million Americans are injured each year by drug errors in hospitals, nursing homes, and doctors' offices.

E-prescribing has the potential to empower both prescribers and pharmacists to deliver higher quality care and improve work flow efficiencies. For providers who choose to invest in e-prescribing technology, quality and efficiency can improve, resulting in better beneficiary outcomes and, more importantly, saving lives.

We continue to make progress on the e-prescribing front. To encourage e-prescribing in the initial year of the Part D program, we published a final rule establishing a set of foundation standards. The rule reflected industry consensus and recommendations from the National Committee on Vital and Health Statistics, which is a Federal advisory committee representing significant experience in health information technology, including e-prescribing. These foundation standards took effect January 1, 2006 and they were related to transaction and eligibility information exchanges among providers, dispensers, and Part B plan sponsors.

In 2006, following implementation of the foundation standards, CMS, along with another HHS agency, the Agency for Healthcare, Research, and Quality, ARQ, conducted a series of pilot tests to test six additional standards for potential adoption. Results of the pilot testing were issued by the Secretary in a report to Congress April of 2007.

Based on the pilot results, several weeks ago, November 15, 2007, we published a Notice of Proposed Rulemaking to adopt two additional standards for e-prescribing in Part D: the first proposed standard for formulary and benefits governs information for prescribers about a patient's drug coverage provided at the point of care; the second proposed standard for medication history is intended to provide a uniform means for prescribers, dispensers, and payors to communicate about drugs that have been dispensed to a patient. The four remaining standards tested during the pilot are not proposed for adoption at this time, but may be proposed in the future.

CMS is committed to continue testing and partnerships with all stakeholders to advance the development of secure, scaleable, and administratively feasible e-prescribing standards for use throughout the health care system. The challenge moving forward is that the law does not treat all prescriptions equally. As the e-prescribing environment continues to evolve, we support a consistent e-prescribing framework because we feel the alternative could slow adoption and generate undue administrative burden, along with attendant incremental costs.

For this reason, CMS believes that existing standards and industry practices must be given careful consideration in future efforts to establish e-prescribing standards, such as those related to controlled substances.

CMS has heard from various stakeholders in both public testimony and in written comments to proposed e-prescribing standards regulation that the inability to prescribe controlled substances electronically is a major inhibitor of overall growth of e-prescribing.

In response, CMS and other parts of HHS have reached out to the DEA to work jointly, along with appropriate stakeholders, to identify and adopt solutions for the secure e-prescribing of controlled substances. These solutions must be consistent and scaleable with current mainstream practices and work flows.

In July 2006, HHS and DEA co-sponsored a public meeting on e-prescribing of controlled substances and solicited input from stakeholders. The stakeholders spoke from various perspectives, but agreed that a consistent approach to e-prescribing was critical.

Following the hearing, CMS and DEA have had further discussions on how best to move ahead, including potential pilot testing. Recently, because of its critical importance to the administration's HIT agenda, we asked Dr. Robert Kolodner, the national coordinator for health information technology, to help broker an acceptable solution. Dr. Kolodner had agreed, and has begun meeting with CMS and DEA.

Thank you for the opportunity to talk about CMS role in promoting e-prescribing. We are committed to ensuring patient safety, not only for the Medicare population, but for all Americans. E-prescribing saves lives, and it is critical to take all necessary steps to achieve widespread adoption of e-prescribing. Thank you.

[The prepared statement of Mr. Trenkle appears in the appendix.]

Senator WHITEHOUSE. Thank you, Mr. Trenkle.

To start at a very basic level, I assume that you two know each other?

Mr. RANNAZZISI. Actually, we just met today. But I think we've been on the phone together, and I know our staffs meet.

Mr. TRENKLE. Yes. Our staffs have met and we've been on the phone with DEA a number of times, I've mentioned.

Senator WHITEHOUSE. And it sounds as if the entry of Dr. Kolodner into this as a broker to force change is a welcome development from both of your points of view?

Mr. RANNAZZISI. Any new perspective, as far as electronic prescribing, is welcomed. Yes, we welcome his perspective as well. Also, Mr. Trenkle testified in that hearing in July, 2006 and it was a very informative hearing.

Senator WHITEHOUSE. I've run administrative agencies and so I have the experience of the triage of priorities that is necessary in an administrative agency. There are those things that sort of urgently must be accomplished, there are those priorities that are things that would be nice to get done but don't have that same urgency, and then there are things that just sort of float around and they're not really urgent, and if you can get to them some day you will, and maybe somebody will push you a little bit to get something done, but it simply isn't in the top first or second tier of administrative priorities.

Where does DEA put getting this done in its hierarchy of administrative priorities?

Mr. RANNAZZISI. It's right at the top of our administrative hierarchies. If you look, historically, back, we started an e-commerce initiative in 1999. In 2005, we initiated a controlled substance ordering system through the use of PKI. The second phase of that would be the electronic prescription initiative. Unfortunately, where CSAS has worked very well, there have been some hang-ups with electronic prescriptions and we're trying to work through them now. But make no mistake about it, it's right at the top of our list of priorities. Again, we started this back in 1999.

Senator WHITEHOUSE. Have you heard from the White House on this issue?

Mr. RANNAZZISI. We've discussed this issue with OMB, yes. With ONDCP, with the Department of Justice.

Senator WHITEHOUSE. When was this?

Mr. RANNAZZISI. OMB, probably within the last month. Within the last week.

Senator WHITEHOUSE. Oh, good.

In your testimony just a moment ago you noted that nearly 7 million Americans have used prescription medications for non-medical purposes.

Mr. RANNAZZISI. Yes.

Senator WHITEHOUSE. And you have said that, nationally, the misuse of prescription drugs was second only to the use of marijuana in calendar year 2005, and far exceeds other illicit drugs—cocaine, heroin, PCP, amphetamines.

Mr. RANNAZZISI. Yes, sir.

Senator WHITEHOUSE. Do you think that the current paper-and-pen regime is a really good model, given that record, in allowing you to prevent the diversion of prescribed controlled substances? And more specifically, in evaluating what the goals are that you seek to achieve for e-prescribing, are you demanding a higher level of effectiveness in that dimension, effectiveness against diversion for the new e-prescribing than you are able to achieve right now through the pen-and-paper system.

Mr. RANNAZZISI. Let's take the second part of the question first. Do I believe that electronic prescribing will prevent diversion? It will prevent some diversion, absolutely, if it's done properly. Yes. We're proponents of the two-factor authentication system. The reason we're proponents of two-factor authentication is because that will help us identify who is actually writing the prescription.

Senator WHITEHOUSE. But to your example a moment ago, you spoke about a small number of pharmacies in which an enormous amount of potentially illicit prescriptions were flowing of hydrocodone, oxycodone. I forget which one you mentioned.

Mr. RANNAZZISI. Right.

Senator WHITEHOUSE. For every document that you no longer have on paper, so your document examiners can't go in and prove the case their way and you actually have to prove the case a different way using electronic signatures—and there are ways to do it. You could do both.

Mr. RANNAZZISI. Right.

Senator WHITEHOUSE. But you would have to change from one to the other. For the inconvenience of that, isn't there a corresponding gain in having all that information at your fingertips and being able to say, you know, there's been a real bulge in prescriptions at this pharmacy that we're noting because it's coming through electronically. We're tracking that in new ways. We can be much more proactive.

It seems to me that the gains of e-prescribing aren't just the gains that HHS is here to advocate for, the gains of patient safety, the gains of greater efficiency, the sort of gateway gains of moving more rapidly to an e-health system for America so we can get away from the health care nightmare we have right now. Those are all

enormous gains. But if you set those aside, it seems to me, are there not also purely law enforcement gains from going to an electronic prescription system for controlled substances?

Mr. RANNAZZISI. Well, I would be speculating now, but until we get a system in place and a pilot in place to actually see how the system operates, I can say probably there will be some law enforcement gains. However, we're not just dealing now with a doctor and a pharmacy, we're dealing with other non-regulated entities that will be involved in the process. I don't know how that's going to pan out. I don't know how much regulatory control I'll have over them. I don't know how they're going to respond to subpoenas. I don't know how the system will address breaches in the system where orders are actually changed.

This is all new to us, and we're trying to work through it. Again, I don't want to speculate. Do I believe that it's going to be better for law enforcement somewhere down the line, once we get the proper system in place? Yes, I do. But currently, right now, I'm just not sure because I don't know what system is in place.

Now, Senator Kennedy talked about that Massachusetts pilot program.

Senator WHITEHOUSE. Why was that shot down?

Mr. RANNAZZISI. That was shot down, not because of the merits of the program, not because of the protocols, but because in their direction what they said was they were going to create a system that would be adopted nationwide for security and controls.

Now, on its face, that doesn't seem like a bad idea, except that's what the rulemaking process is. For us to agree to that, we'd be hijacking the rulemaking process. We didn't disagree with the merits of that pilot. In fact, we're working with Massachusetts right now for them to resubmit so we can approve it. So it's not been shot down, we're just in the process of trying to work with them to get their protocols back in so we could approve it.

Senator WHITEHOUSE. My distinguished colleague, Senator Coburn, has joined us. I have been taking the floor for a while now in asking a number of questions, so if you would like to step in, Senator, I would yield the floor to you.

Senator COBURN. It's curious to me, with all the benefits that we're going to get from e-prescriptions, why you all would not say, here are the things we have to have as you do this. In other words, rather than worry about the "what ifs", why don't you tell us what the "what ifs" are and have us write legislation that covers it? There is no question, consumers are going to be better off in this country with the pharmacist not reading my handwriting. There's no question about that. There is no question that control of controlled substances is going to be far improved with e-prescriptions. Will there be new potentials for abuse? Yes. Will there be new loopholes?

But I think, reading the history on this last night, it seems to me that the problem is, the DEA needs to tell us, here are the things we're concerned about, fix that as you write this, and you change this, rather than saying we can't get there. We have to get there. We have a lot of problems in terms of IT interoperability now in health care, and that's something the administration is

doing a great job on. They don't need a piece of legislation for it. They're actually accomplishing it under Secretary Leavitt now.

But assuming that the interoperable standards are going to be there and that the medical community and the health care community is going to eventually go online with medical records, et cetera, to say that we can't come up and lead on what is necessary—I'd just like your comment. Why wouldn't you just give back to this committee, here's the things that we think have to be included in anything that has to happen in terms of e-prescriptions for controlled substances, and then let us work with you as we formulate legislation to create that so that we have the safeguards against abuse of controlled substances?

Mr. RANNAZZISI. Well, Senator, I believe we've gone on record numerous times as saying the three things that we need are authentication, non-repudiation, and a system that protects the integrity of the recordkeeping process. The devil is in the details. I would love to sit here and give you a laundry list of things that we need. Technically, I'm not the person to do that. That's what I have a technical staff for.

However, they are just as cautious of developing these protocols as I am because they know that we have pretty much one shot to do it right. If we don't do it right, there could be a massive problem in the system which causes a lot of diversion, a huge avenue of diversion. That's what a pilot program is for. That's why this pilot is important to us. In fact, Massachusetts' pilot was just resubmitted last Thursday and we're in the process of reviewing it now. If we can get that pilot up and running, we'll have a better idea of how the system works.

Senator COBURN. There is a massive amount of diversion now.

Mr. RANNAZZISI. Yes, there is. And we don't want to contribute to that.

Senator COBURN. But not looking at the opportunity for eliminating what's there now by going to an e-prescription would seem to me—you have a shop. You can offer suggested legislative language that would raise your concerns on that, that would address every concern that the DEA would have.

Mr. RANNAZZISI. Being in the rulemaking process right now and drafting proposed regulations, I think we're requesting more time to get this right. I would love to give you language for legislation, but we're so far along in the rulemaking process right now, the regulation process right now, I think if you just give us a little more time we'll have something that we'll all benefit from.

Senator COBURN. What is "a little more time"?

Mr. RANNAZZISI. That's the question of the decade. If the Drug Enforcement Administration was the approving authority, the sole approving authority for all rules and regulations, as the head of the Office of Diversion Control I would give you a time. But it's not. We have to go through a process of vetting with several agencies and several different components of the administration. If I sat here and gave you a time limit, I'd be lying to you and I don't want to do that.

Senator COBURN. Good. Give us the time at which you will offer that vetting to the other agencies.

Mr. RANNAZZISI. At this point in time I don't believe I'm able to do that.

Senator COBURN. Is there a time at which you will be able to give us that?

Mr. RANNAZZISI. Yes. I'd like to see, once Massachusetts is up and running, how their program is working.

Senator COBURN. That's a little bit frustrating, just to be quite honest with you. The fact is, you're responsible for control of—

Mr. RANNAZZISI.—Yes, I am.

Senator COBURN [continuing.] Controlled substances in this country, and there is no question, it's an indisputable fact that we're going to have a better handle on it if we do it in a more advanced technological way. E-prescriptions is that way. The idea is, you don't want to go on record to be held to account; because somebody might hold you to account is why we're not going to get there as soon as we should get there. Every day we don't get there, somebody dies from an overdose. Somebody puts somebody else onto a drug. We see more drugs on the street. The fact is, we're talking about ways to actually improve the DEA, the capability to enforce and do its job. I will submit some letters, some questions in writing. But I don't think that's an acceptable answer of not getting this point.

Senator WHITEHOUSE. I agree.

Senator COBURN. There ought to be a time at which you can, with your staff, say we will have a position of DEA on e-prescribing that raises the areas that we think are a problem, at which time we will submit for vetting for the rest of the administration. We'll do the oversight. I think Senator Whitehouse has proven that he's capable of doing the oversight.

If you've submitted it and we know it, then we'll be bringing everybody up here and saying, "What's wrong with it?" The fact is, we need to get there. We're behind the rest of the world in terms of IT and health care. This is a large component that's going to make a big difference in terms of offering health to people and safety to people. So, I just think that we need to have a date from you. You all know the process.

I'm very supportive of DEA. I know that a lot of the problems with controlled substances is physician-based because we don't do our job, or we don't do it the way we should. But this is an area of expertise and of a technical nature that you all have, and can have, and can offer. We ought to have a time frame. My fear is, we're going to be sitting here 2 years from now doing the same thing because the pilot didn't go as you wanted. So what if the pilot doesn't go? If you know what you want and you know what you need, we can solve the problem. But we can't if we don't start. The starting point has to be with you all saying here's what you'd like to have.

Mr. RANNAZZISI. Sir, we look forward to working with this committee, working with your staff and Senator Whitehouse's staff. We'd be more than happy to provide briefings for you on where we are and how we're going about the process. I regret that I can't give you a date, a hard date. I would love to give you a hard date. I'm a health professional. I'm a pharmacist, a registered pharmacist by trade, so I understand the problems. But I just think it would be

foolish for me to give you even an estimate because I'd just be speculating.

Senator COBURN. So there's nothing inside your organization today that says "we have a goal to get there X"?

Mr. RANNAZZISI. Yes, there is.

Senator COBURN. And when is that? When is that X?

Mr. RANNAZZISI. We have a goal to get to a particular place, but we don't have a time period yet. I can tell you, we are drafting regulations. We've been in contact with HHS. We've discussed our regulations with the department. We've discussed our regulations with ONDCP. It's in the process. However, I just can't give you a hard date. Again, that would be reckless for me to give you a hard date. When? Trust me, as soon as possible, as far as I'm concerned.

Senator COBURN. Thank you. I don't have any other questions.

Senator WHITEHOUSE. Nothing that you have told Senator Coburn about the administrative process and the accountability for the administrative process is consistent with your earlier testimony that this is a top priority for the Drug Enforcement Administration. I simply can't believe that if this is something that is viewed by the Drug Enforcement Administration as a top priority, there isn't the kind of internal scheduling for purpose of internal administrative accountability that you would set up.

When I've run organizations and I want to get something done, I lay out what I expect to get done and I tell people it's got to be done by this date, and I can hold my staff accountable. Accountability makes action take place in government.

So I think for both of us to hear you say, well, we don't know what date, we don't have a date, we're not sure, we want generally to do it as soon as possible but nobody's actually pinned down any accountability points for this, none of that registers with us as resembling "top priority".

Mr. RANNAZZISI. I don't think you compare prioritization of tasks with a staff than with an agency that has to deal with several other agencies, in addition to several administration components. The fact is, when we're drafting the rules we don't do it in a vacuum. We're in constant contact with the agencies that we work with, bouncing things off of them.

Senator WHITEHOUSE. But everybody else is pushing to get this done. DHS would like to have this done yesterday. OMB wants this to move. Somebody just assigned Dr. Kolodner to try to solve this. I mean, it's not as if other people are holding you back. At least, that's not the way it seems.

Mr. RANNAZZISI. And obviously CMS and several different agencies have reasons why they're pushing it, and their reasons could be different than DEA's. The fact is, we have to protect the public health and safety from diversion of controlled substances, and to do that we have to—

Senator WHITEHOUSE. Let me stop you right there.

Mr. RANNAZZISI. OK.

Senator WHITEHOUSE. Every agency has its purposes. From a public policy point of view, we need to see that decisions are made in the best interests overall. We can't have an agency stopping a process because it has particular concerns, however well founded those may be, if the externalities, the benefits of this going forward

in other areas are so enormous that, on a cost/benefit calculation for society, for America, for people who are out there stuck in our health care system right now, this is a big loser. You've got to be prepared to kind of move on and work with other people for the greater good.

If I could just, for a moment, ask Mr. Trenkle to summarize, he touched on safety issues, he touched on efficiency issues, he touched on improvement of care, and he touched on this as sort of, I'm calling it the "gateway" factor, that this can be a progress step toward an electronic health system for America that can reap enormous rewards, and we're holding back on that progress here. While, on the internal calculation with respect to DEA, whether you will do drug diversion more effectively or not—and I suggest, given the results we're seeing right now it's hard to imagine it's going to turn out a whole lot worse. It's sort of the number-one drug abuse problem in America right now, I would hazard. So the idea that it's going to end up a whole lot worse with this technology is a little bit hard to believe. But when you compare it with the public benefits that HHS is arguing for, it seems to me that it's worth taking that shot. Let's just get it out there and cope. You do your best to make it happen, but you don't stop all this other progress because your particular interest isn't met.

Would you react to that?

Mr. RANNAZZISI. Yes. Controlled substances are a different type of drug than non-controlled substances, or legend drugs. The fact is, that's why Congress created the CSA, because they recognized the abuse potential of these drugs. That's why they took it out of the FDCA, put it in a separate category. In my 20-plus years of law enforcement, I've never seen anybody selling amoxicillin, Indural, or any of those other drugs out on the street, but I do see them selling Vicodin.

And there's a reason for it, because the profit potential and the abuse potential of those drugs are incredibly higher. So while on the legend drug side you might not need the security because you're not going to see the diversion, you will see it on the controlled substances side. That's why we're moving so cautiously.

Senator WHITEHOUSE. My problem, Mr. Rannazzisi, is you are answering the question in exactly the mode that I'm trying to push back against, which is that, in this case it is all about our diversion responsibilities, when in this case I think it's all about a lot of other issues as well. It's all about, also, patient safety, which will be dramatically improved if we can get to a serious e-prescription regime.

It is all about far greater efficiency and cost when families are out there right now getting creamed with prescription drug costs if they have a seriously ill member of the family. It's all about allowing our health care system to develop into a system that is truly supported by information technology and has comprehensive electronic health records.

All of these things are being affected by this decision. I'd like to hear from you that, from an administrative point of view, you recognize all of those benefits, and it's not just about the internal balance between, is this better or worse from our diversion point of

view, but that this is a larger issue and maybe needs a little bit more attention for that reason.

Mr. RANNAZZISI. As I said before, I think the benefits of electronic prescribing are numerous. I understand that electronic patient records are very important. I understand that it's a very good cost-saving measure. I understand that it could prevent a lot of the medication errors and interactions—not all of them, but I'm pretty sure most of them. OK. However, again, that aside, I have to look at other things.

Now, there's no question that there are benefits.

Senator WHITEHOUSE. Do you look at that thing?

Mr. RANNAZZISI. Yes. Absolutely. Absolutely. I just said I did. But that's—unfortunately, there are other factors involved that we have to look at. We're protecting the integrity of the closed system of controlled substance distribution, and to do that there are other factors that we look at. I'm not saying that the electronic prescribing of drugs in general is not beneficial universally. It is. But we have to do it properly. We have to do it appropriately. We have to do it so it's not going to create another avenue of diversion.

Senator COBURN. Mr. Chairman, can I?

Senator WHITEHOUSE. Please.

Senator COBURN. Two years from now, will we have a system?

Mr. RANNAZZISI. I would hope so.

Senator COBURN. But you can't say "yes, we will"? We're getting to that Coburn's Theory of Bureaucracy: never do what's best when you can do what's safe. Now, I understand you're a safety agency. But the goal is hiding behind a message that allows you not to step up to the line. That's what I'm hearing, and that's what I don't like. It has nothing to do with you personally, Mr. Administrator. It has to do with the fact that everybody else that's sitting here watching this hearing is saying, why couldn't they do it in 2 years? Why couldn't it get done in 2 years?

The question is, obviously it could if people committed to it and did it. But what we have is no commitment, which is worrisome because we may be here 2 years from now with the exact same problem on controlled substances. My dealings with the DEA in the past have been very, very similar in terms of responsiveness. So, you need at least to give the committee some type of assurance we're going to get this problem solved in some timeframe. If you say "three years", great, 3 years. But to not say anything means that you're not going to step up to the line and say, here's something we need to do for this country.

Mr. RANNAZZISI. Sir, I would hope that within 3 years we have a system in place. My personal goal is quite a bit shorter than that, but in 3 years I would hope to have some system in place, yes. You know, obviously it's a personal goal to have it a lot quicker. But, you know, if you're asking me, for 3 years, I believe that in 3 years some system will be in place, yes.

Senator COBURN. Have you communicated with your staff that this is something we're going to get done and we're going to get it done in a certain timeframe?

Mr. RANNAZZISI. My staff is right behind me here and—

Senator COBURN. No, no. I said, have you communicated to your staff that, this is our goal, this is what we're going to get done, and we're going to get it done in a certain timeframe?

Mr. RANNAZZISI. I've communicated to my staff that we have a goal and we want to get to it as quickly as possible, however, with the appropriate safeguards to protect the integrity of the closed system. Yes.

Senator COBURN. But every agency head in this Federal Government can answer a question that way. What I'm saying is, have you set a goal, a time goal, within your staff to get something done?

Mr. RANNAZZISI. No, I can't set a time goal, sir.

Senator WHITEHOUSE. Let me ask you a different question. DEA agents out in the field. I was U.S. Attorney in Rhode Island. We had a wonderful DEA office in that district. The agents communicate with each other how? Do they communicate with each other electronically?

Mr. RANNAZZISI. The whole agency communicates electronically through an e-mail system, yes. A secure e-mail system.

Senator WHITEHOUSE. And that system is kept secure?

Mr. RANNAZZISI. There are security safeguards built within the system, depending on the system you're using, yes.

Senator WHITEHOUSE. And they're adequate for the DEA to have taken that step and gone to electronic internal communication. Correct?

Mr. RANNAZZISI. Yes.

Senator WHITEHOUSE. And highly confidential investigative and other material is transmitted through that system between offices and from agents back to headquarters?

Mr. RANNAZZISI. Depending on the level of security of the information, no, not necessarily. We have several different systems to pass information depending on the level of security necessary for that information.

Senator WHITEHOUSE. But you're comfortable that you can transmit electronically within DEA highly confidential investigative information at the appropriate level of security, correct?

Mr. RANNAZZISI. Yes. Absolutely.

Senator WHITEHOUSE. And you do that day in and day out. It's happening right now over at the DEA.

Mr. RANNAZZISI. Yes.

Senator WHITEHOUSE. And you have a database, don't you, that keeps track of evidence of suspected drug dealers, of suspected drug networks, of suspected drug organizations and how they connect, and who is involved, and how they're financed, and all of that? You have a very extensive intelligence aspect to try to investigate drug dealing organizations inside and outside the country, don't you?

Mr. RANNAZZISI. Yes, we have intelligence databases. Yes.

Senator WHITEHOUSE. And you keep those databases electronically, don't you?

Mr. RANNAZZISI. Yes.

Senator WHITEHOUSE. And you're comfortable that they can be kept securely?

Mr. RANNAZZISI. Yes.

Senator WHITEHOUSE. All right. It would be nice to try the same thing for a guy who wants to prescribe a bottle of Vicodin.

Mr. RANNAZZISI. I understand your concerns, sir.

Senator WHITEHOUSE. What is the view from HHS as to where we are procedurally on this? What are the next steps? What does Secretary Leavitt anticipate as a deadline for this process? When, from HHS's point of view, should we expect to have e-prescribing in place in the United States of America for controlled substances?

Mr. TRENKLE. From the HHS perspective, obviously we're in support of e-prescribing as much as possible, as soon as possible. As you know, over the last 2 years we've not only promulgated two sets of standards, we've also run five pilot projects that report to Congress. So, we're moving as quickly as possible to move ahead in e-prescribing and we stand here ready to work with DEA as much as possible on a pilot project, to assist them in providing background, feedback, anything to support their regulations. We feel, as you know, Senator, that this is a very major area for patient safety. It's a key element of the interoperable network that we're pushing, both within e-prescribing and HIT as a whole.

Senator WHITEHOUSE. Is that, by the way, why the 2004 proposed regulations were requested by the Department of Justice to be withdrawn, because of non-concurrence with HHS? Is it because of the interoperability issue, and to have this be something that can link in with the prescribing network?

Mr. TRENKLE. Yes. We were concerned, as I mentioned in my testimony. We would like to build an e-prescribing system that incorporates what's in the current system, and in addition takes into account DEA's requirements, but not to build something that would potentially require two systems.

Senator WHITEHOUSE. A parallel and independent system. Yes.

Mr. TRENKLE. Correct.

Senator WHITEHOUSE. Good. I think that's a sensible goal.

Is that a goal that DEA shares, that a doctor who's prescribing amoxicillin and Vicodin should be able to go to the same machine and enter the prescription when they send it down to CVS or to Rite Aid?

Mr. RANNAZZISI. Yes, sir. We don't want parallel systems. We don't think that serves any purpose, other than to probably push doctors away from prescribing through electronic means. So, yes, we share that goal.

Senator WHITEHOUSE. Good. Well, what I would like to do, is ask a question for the record of the Administrator, the Acting Administrator, that she provide to this committee the very best and most concrete information that she can give us that will answer Senator Coburn's question and my question about what the timeframe is for the administrative process of concluding the e-prescribing rulemaking.

That would include not only an end date by which somebody is willing to be held accountable for saying "I will get this done by then", but also any steps along the way, the announcement of a proposed rulemaking, for instance, with the various Administrative Procedures Act steps. If any of them are at this point timed, or if you can get back to us with a time that you're willing to commit to, because we really do need to know what is going on and when

this is going to happen. You've seen intense bipartisan concern about this.

This is not an issue where we're going to go away. We'll be back at you regularly on this subject. I think, when you consider some of the costs that are involved here, which I submit that you have not adequately recognized as an agency, the costs in patient safety, the 530,000 episodes of adverse drug interactions. Every one of them is an individual or a family that is frightened, that is harmed, that is put at risk, times 530,000. That's a lot of pain. We have a miserable health care system in this country, with terrible information technology support right now. We need to move rapidly toward developing information technology support for our health care system.

I think it is probably Secretary Leavitt's primary, single goal. It's something that the President has spoken about, he's appointed people to be in charge of. It's a very high priority that will affect businesses across the country which are now non-competitive with foreign manufacturers who don't have to put that much health care into their products, and they're at a big price disadvantage.

It's really difficult for the American families who have to live through the tragedy of the health care system that doesn't help them when they need it. Some of those are insured families who find that they're in a nightmare, despite the fact that they thought they had adequate insurance. So, there's a lot at stake here. I think it's important that the different elements of the administration be willing to look beyond their own brief and consider more broadly the cost/benefit to the country of getting past this, and move with according dispatch.

I carry a little book around and I write things in it that interest me, that I think are useful thoughts to keep. I have one that I will close this part of the hearing with, which is a quotation from a decision of the U.S. Supreme Court in an opinion authorized by the great Justice Holmes, Oliver Wendell Holmes.

He said, "All rights tend to declare themselves absolute to their logical extreme, yet all, in fact, are limited by the neighborhood of principles of policy which are other than those on which the particular right is founded and which become strong enough to hold their own when a certain point is reached." I think we are at the point in which the neighborhood of principles around drug diversion authority needs to assert itself.

It's no longer appropriate for the Drug Enforcement Administration to treat the diversion question alone as being the absolute here in this public policy question. I appreciate that you've come here. I appreciate, you've taken a lot of bullets today. I know that you are the single human representative of a large organization, and that there are some things that are beyond your control. But we have a job here as well. Sometimes that job is to be a thorn in the side of the executive branch to spur activity. I'm sorry that you had to be at the point in the body where the thorn was applied today, but I'm sure you understand that we are here in good faith to try to solve an important problem for our country.

Mr. RANNAZZISI. I understand and respect your role, Senator. I appreciate those words. I will take this back to the Acting Administrator.

Senator WHITEHOUSE. And the question for the record is one that, if you could commit to at least a time in which that question will be answered: 30 days, 60 days?

[Laughter.]

We'd like to leave here with at least one firm date. When can you get back to us with the answer? Sixty days? Thirty days? Two weeks? You name it.

Mr. RANNAZZISI. To get back with the answer?

Senator WHITEHOUSE. Yes. We're getting concurrence here. Good.

Mr. RANNAZZISI. I would say within 60 days.

Senator WHITEHOUSE. Sixty days it is.

Mr. RANNAZZISI. Yes.

Senator WHITEHOUSE. I appreciate it. If you could make sure that it's returned not only to me, but also to Senator Coburn, who has shown such a distinct interest in this.

Mr. RANNAZZISI. OK.

Senator WHITEHOUSE. I thank you both for your testimony and I look forward to working with you in the months ahead to work our way through this quandary and get this resolved. I thank you both kindly.

We'll take a few minute break while the next panel gathers. We'll break for 5 minutes.

Mr. RANNAZZISI. Thank you, sir.

[Whereupon, at 11:05 a.m. the hearing was recessed.]

AFTER RECESS [11:09 a.m.]

Senator WHITEHOUSE. Let me call the hearing back to order and welcome the second panel. I am grateful that you all are here. I appreciate it very much. You have all been interested in, and helpful with, this question. We look forward very much to your guidance and advice on this important matter.

Some of you, I know already. I'm delighted to welcome Laura Adams here from Rhode Island. She's not actually from Rhode Island, but she works in Rhode Island and is the executive director of an organization called the Rhode Island Quality Institute, which has been a leadership organization in bringing together the various stakeholders in the Rhode Island health care system to improve information technology and explore energetically that very special area in which improving the quality of health care lowers the cost. It's an area well worth mining, and she's done a wonderful job. I'm delighted that she is here.

Kevin Hutchinson is the president and CEO of Sure Scripts. He has worked with us in Rhode Island also. He has led the effort to establish a neutral nationwide network for electronic prescribing by connecting the Nation's numerous physicians' technology applications and pharmacy software systems, enabling physicians and pharmacies to communicate electronically. Notably, Secretary Leavitt has selected Mr. Hutchinson to serve as one of the 16 Commissioners of the American Health Information Community, so he is a national leader on this issue as well.

David Miller is the Chief Security Officer for Covisint, where he directs and implements internal and external system architectural security solutions for the multi-industry exchange. In addition, Mr. Miller directs the federation and identity management offering at Covisint, which currently secures access for other 300,000 users

across the health care and automotive industries, as well as various public sector initiatives.

Michael Podgurski has been at the Rite Aid Corporation since 1987, where he current serves as Rite Aid's vice president of Pharmacy Services. He's the past chairman of the Pennsylvania State Board of Pharmacy, hence the appearance today and the recognition today from your wonderful Senator, Arlen Specter. I'm so glad that he was able to come and welcome you.

He has served on both the Committee on Law Enforcement Legislation and the Task Force on Pharmacy Automation at the National Association of the Boards of Pharmacy, so he is perfectly positioned for this discussion today.

I welcome all of the witnesses. I would ask that you stand as a group so that I can administer the oath.

[Whereupon, the witnesses were duly sworn.]

Senator WHITEHOUSE. Thank you very much. Please be seated.

Why don't I ask each of you to make a summary of the file testimony rather briefly, and just go right down the table. Then we can have a bit more of a dialog. It should be a little bit more of an open forum than if we just go one back and forth.

So if you don't mind, I'll ask Ms. Adams to proceed.

STATEMENT OF LAURA ADAMS, PRESIDENT AND CEO, RHODE ISLAND QUALITY INSTITUTE, PROVIDENCE, RHODE ISLAND

Ms. ADAMS. Thank you, Mr. Chairman. For the record, my name is Laura Adams and I'm the president and CEO of the Rhode Island Quality Institute. This is a not-for-profit organization founded 6 years ago by then-Attorney General of Rhode Island, now U.S. Senator, Sheldon Whitehouse.

This multi-stakeholder organization, comprised of hospitals, physicians, nurses, consumers, insurers, and employers has the singular mission of significantly improving the quality, safety, and value of health care in Rhode Island. We have no other agenda and we are beholden to nobody but the people of the State of Rhode Island.

I believe, Senator Whitehouse, I remember vividly you putting a fine point on this about 4 years ago for the members of the Institute when we were exploring the value of electronic technology in health care when you pointed out to all of us that anybody just has to go through a fast-food restaurant and watch your order come up on the screen to realize there's more technology in getting your hamburger from your fast-food restaurant than there is in getting your medications to patients. That point never left us.

I am here today to respectfully request that the committee take action to strongly urge the Drug Enforcement Administration and the Department of Justice to promulgate regulations immediately for electronic prescribing of controlled substances that are technology neutral, that build on today's safe and secure electronic prescribing infrastructure, allow for future changes in growth of technology, privacy, and security safeguards in industry expansion.

I'm going to speak about the need for those new regulations from the perspective of our broad-based coalition that's working together to transform the health care system in the State of Rhode Island. The Quality Institute serves as Rhode Island's regional health in-

formation organization, or RHIO. We strongly believe in the value of health information technology as an essential element of any viable proposal for addressing the problems that plague our health care system right, left, or center.

It's our goal to bring about the delivery of health care system in our State, and bring it out of the paper-based system, which we recognize as a root cause of significant waste and harm and is a horrendous barrier to innovation.

In order for the people of our State and our Nation to realize the promise of health information technology globally, their providers have to adopt it and use it. Our job in Rhode Island is to work diligently to lower these barriers to adoption. Our Clinical IT Leadership Committee, a group of some of the most competent and respected thought leader physicians in Rhode Island, has identified the inability to electronically prescribe controlled substances as a significant barrier to adoption.

Some physicians on our committee, who devoted their scarce and valuable time to this work for more than 3 years, have cited this barrier as one of the primary reasons that they, themselves, have not yet adopted electronic prescribing, even though they're absolutely, unequivocally sure of the benefits to patients, providers, and payors.

While approximately 12.5 percent of all prescribed drugs are controlled substances, perhaps a more significant number is the far higher percentage of patients that require the prescription of controlled substances in addition to medications that are permitted to be electronically prescribed.

For example, in the very common situation where an elderly patient needs multiple medications to manage their chronic illnesses and some of the drugs are controlled, it makes it far more likely that a very busy practitioner who has adopted electronic prescribing will default to the paper-based system for all of the prescriptions for that particular patient than attempt other than operating parallel systems and their very complex office settings.

Therefore, the inability to electronically prescribe controlled substances not only thwarts adoption in the first place, it suppresses the total number of electronic prescriptions written by those who have adopted and want to electronically prescribe.

As I'm sure every member of the committee knows, research has shown that medication errors are occurring at an alarming rate in this country. With a staggering number of new drugs on the market and more and more coming out all the time, it's become all but impossible for providers to rely on their memory for proper dosing, avoidance of drug-drug interactions, and allergic reactions. I think David Eddie said it best when he said that "the complexity of modern medicine has exceeded the capacity of the unaided human mind."

Controlled substances include some of the most potent and potentially harmful drugs, if given in the wrong dose or with other drugs that result in untoward reactions. When a misplaced decimal point or a drug interaction can be catastrophic—death by decimal point, if you will—these patients are effectively being denied a system that could save their lives. Patients who require controlled sub-

stances deserve the same opportunity for safer prescribing as all other patients.

Another problem of great concern to emergency room physicians in Rhode Island is the electronic prescription of controlled substances prevention. It doesn't help them prevent "doctor shopping", when patients with addictions or drug dependency problems go from physician to physician to obtain controlled substances. I was urged by the emergency room director of our largest institution in Rhode Island to bring this issue up today.

Electronic prescribing by emergency room physicians can help to identify patients who doctor shop much more quickly and efficiently than is now possible. This creates an immediate electronic footprint or an audit trail that is documented and time stamped through each point in the process, from the prescriber's location to the pharmacy.

This is not simply an e-mail over the Internet, not by a long shot. So that is not to say that electronic prescribing of controlled substances, in every instance, could prevent drug diversion. But it is saying that it can go a long way toward reducing incidents of doctor shopping, reducing the rate of those who successfully forge prescriptions, or alter the originals.

We are asking today. The industry is ready. The need has never been greater. We are asking for your help to bring about the electronic prescribing of controlled substances and all the benefits it affords consumers, providers, and payors.

Thank you for the opportunity to come before you today with this request.

Senator WHITEHOUSE. Thank you, Ms. Adams.

[The prepared statement of Ms. Adams appears in the appendix.]

Senator WHITEHOUSE. Mr. Hutchinson.

STATEMENT OF KEVIN HUTCHINSON, CEO, SURE SCRIPTS, ALEXANDRIA, VIRGINIA

Mr. HUTCHINSON. Chairman Whitehouse, I thank you for the opportunity to testify on this very important topic. We at Sure Scripts have been interested in the implementation of electronic prescribing for controlled substances for several years and we're pleased to share our experiences and views on this very important matter.

We were created by the National Community Pharmacists Association and the National Association of Chain Drugstores in 2001. Our mission is to improve the overall prescribing process and to ensure, among other things, neutrality, patient safety, privacy and security, and enforce a patient's ability to choose their pharmacy, and a physician's ability to choose the appropriate therapy without encountering any commercial messages along the way.

Under the leadership and with the backing of the pharmacy industry, Sure Scripts has created a neutral and secure network that is compatible with all major physician and pharmacy software systems.

What is electronic prescribing? Put simply, it is not an e-mail. It is the private and secure electronic delivery of prescription and other health care information from a prescriber's computer to the computer of the pharmacy, and back again.

Allow me to point out what the term "e-prescribing" does not include. It is not using a computer-generated fax. It is not sending a prescription in an unsecure manner over the Internet. It does not entail unlicensed or rogue Internet pharmacies. The pharmacies that are connected to the network are duly licensed and legitimate retail and mail-order pharmacies.

The company's services were first put into production sending and receiving electronic prescription transactions in January of 2004. Today, more than 95 percent of the Nation's pharmacies have computer systems that have been certified for connection to the Pharmacy Health Information Technology Exchange. Seventy percent of the Nation's pharmacies are live on the network today.

In addition, physician software vendors, including electronic medical record vendors and stand-alone e-prescribing applications, whose combined customer base represents well over 150,000 prescribing physicians, have contracted and certified their applications in the Nation's Pharmacy Health Information Technology Exchange.

Electronic prescribing with respect to non-controlled substances is a reality today. In 2007, 35 million prescription transactions will have been routed electronically in the U.S. Over 35,000 prescribers will have been utilizing e-prescribing in the U.S., and over 40,000 pharmacies will have been e-prescribing in the U.S. This represents 70 percent of the pharmacies in the United States.

In fact, more prescribers electronically prescribed in the first 10 months of 2007 than in all of 2004, 2005, and 2006 combined. There were more electronic prescriptions transmitted in the first 8 months of 2007 than in all of 2004, 2005, and 2006 combined as well.

For 2008, Sure Scripts estimates the number of prescription transactions routed electronically will grow to over 100 million. We estimate that in 2008, the number of electronic prescribers will grow to approximately 85,000. Finally, for 2008, Sure Scripts estimates the number of e-prescribing pharmacies will grow to 45,000.

Today, Sure Scripts is issuing the "National Progress Report on E-Prescribing", an at-a-glance summary of key statistics detailing the status of e-prescribing adoption and utilization in the U.S. The deployment and use of electronic medical records is a bipartisan priority of Congress, as well as a priority of President Bush's administration. The automation of the prescribing process is considered by many to be the first step in the deployment of robust electronic medical records. Many would argue that if we cannot get providers to take the first step of e-prescribing, then how will we expect them to adopt a full-fledged electronic medical records system?

Federal policymakers and a growing number of congressional and State legislators are calling for e-prescribing of controlled substances to enable public and private payors, consumers, and others to take full advantage of the safety benefits, quality of care improvements, and increased cost savings accruing from e-prescribing.

Adoption and utilization of e-prescribing is on the rise, but there are still barriers to adoption. One of those significant barriers is the fact that prescribers cannot process controlled substances elec-

tronically. This prohibition directly affects more than 11 to 13 percent of prescribed medications in the U.S. today.

Prescribers want, and need, to use just one tool and one process to prescribe their patients' medications. Using one process for one drug and another process for a second drug is inefficient, dangerous, and unnecessary. Consider a physician that's about to prescribe both controlled and non-controlled medications to his or her patient but cannot use electronic prescribing for all of the prescriptions.

As a result, prescriptions are written electronically in which an automatic drug interaction check is performed, and the remaining drugs, which are controlled substances, are written by hand and no drug interaction check is performed against those medications, leaving the patient vulnerable to an adverse drug event. The more likely case, is the prescriber chooses to just use the paper and pen to issue all of the patient's prescriptions and the advantages of automatic drug interaction checks and use of available clinical decision support tools is lost.

Time and time again, we hear from prescribers that they will not e-prescribe, at all because they cannot controlled substances electronically. Accordingly, the DEA prohibition affects not just the 11 to 13 percent of controlled substances, but a far greater number of prescriptions. This is truly a barrier to adoption.

We agree that the criminal element is interested in leveraging today's paper-based process using fraudulent means to obtain Schedule II through V drugs, and we absolutely agree that the DEA and other law enforcement officials need the necessary tools to find and prosecute those who abuse drugs and break the law.

We believe, however, the current system used for e-prescribing supports the highly secure transmission of prescriptions, regardless of Schedule. We believe that today's system of e-prescribing would enhance, not deter, law enforcement. E-prescribing is far safer and more secure than today's paper world in which prescription pads are stolen, home computers can easily print out counterfeit prescriptions, signatures can be scanned and forged easily, and drug quantities can be altered manually by patients before prescriptions are delivered to the pharmacy.

In fact, Congress has always concluded that e-prescribing is a substitute for paper and pen with respect to the prevention of fraud. In Section 7002(b) of the U.S. Troop Readiness, Veterans Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007, Congress mandated the use of tamper-proof pads for all Medicaid prescriptions. It significantly allowed for e-prescribing as an alternative to even tamper-proof paper.

Among other things, the law aimed to prevent patients from illegally obtaining controlled drugs. Accordingly, Congress has also recognized that e-prescribing prevents fraud as much, if not more than, the vulnerable paper- based system that exists today.

The current e-prescribing system also allows for the tracking of prescriptions on a real-time basis, which is not possible, at least in a timely and scaleable way, with paper processes in place today. E-prescribing could help law enforcement to quickly identify in real time patients who doctor shop and garner multiple prescriptions for controlled substances.

E-prescribing, additionally, creates an immediate electronic audit trail that is documented and time stamped through each point in the process, from the prescribing clinician's office to the pharmacy. These electronic audit trails show who touched the prescription, and when.

If the prescription is created and sent electronically, these built-in audit trails also could be used to identify drug shopping if the patient pays cash. These electronic records, available from the proactive process that is now live in all 50 States, including the District of Columbia, when subpoenaed, could assist law enforcement in prosecuting diversion cases in a much more timely and efficient manner than today's e-prescribing process.

Accordingly, we call upon Congress to encourage the adoption of regulations that would allow for electronic prescribing of controlled substances. Such regulations should set forth policy that achieves the goals and mandate of law enforcement authorities and not mandate particular technologies. E-prescribing, as currently conducted, not only will enhance law enforcement, but will advance a legislative agenda promoting electronic health records, which will save the Federal Government millions of dollars, and will save lives.

We are Sure Scripts thank the committee for the opportunity to share our experiences with respect to electronic health care, and it would be my pleasure to answer any questions you might have.

Senator WHITEHOUSE. Thank you, Mr. Hutchinson. I appreciate it.

[The prepared statement of Mr. Hutchinson appears in the appendix.]

Senator WHITEHOUSE. Mr. Miller.

STATEMENT OF DAVID MILLER, CHIEF SECURITY OFFICER, COVISINT, DETROIT, MICHIGAN

Mr. MILLER. Senator Whitehouse, I appreciate the opportunity for myself and Covisint to be able to talk about the issues associated with e-prescribing. Although in the last few years Covisint has supported many doctors and pharmacies related to things like RHIOs, and also supports the current law enforcement information sharing program, that was not our birth. The birth of Covisint was in 2000, really based upon the automotive industry.

I am really here to tell you that this problem of secure transaction sharing among large organizations that may not trust each other, where there is the capability for fraud, has been solved in other industries. This is not a brand-new thing. This is not something that has never come up before.

Covisint, having to bear this problem in automotive, has found some techniques in order to do this. The automotives, very early on, realized that there was going to be a need to go to electronic transactions. A large automotive manufacturer does billions of transactions every month, and it's gotten to the point, with global awareness, with global suppliers, that you just can't do that with paper. You can't put pieces of paper in an envelope and send it. So, certainly in the 1990's, they decided to go to an electronic means.

In 2000, Covisint was started to leverage this new thing called the Internet, to be able to make it more effective and cheaper, real-

ly, to be able to do these type of electronic transactions. These transactions moved to electronics. I can tell you for a fact, having been in the automotive industry then, that there were a lot of issues associated with security of that type of thing.

Here's what was found out. What was found out, is that electronic transactions have a few things that paper-based transactions just don't have. They have easy auditability, so they are truly auditable because you can send them through some sort of centralized system, you can count them in the hundreds of millions.

They are trackable in real time. So is it really effective to be able to find out that somebody is prescribing drugs that they weren't supposed to be prescribing 6 months after that event occurs? Real-time action is very important.

They're transparent. And by "transparent" I don't mean insecure, and I don't mean that HIPPA-based information is exposed. By transparent, what I mean is, it is very difficult for two parties to collude and get around the system, as it is much easier in paper-based transactions.

You can take a look at historical information. I would assume that there are hundreds and hundreds of millions of transactions on controlled substances. Can you see the types of things—doctors and pharmacists who are probably getting around the system oftentimes use things that maybe aren't quite so obvious. But perhaps by looking at months and months' worth of records, or years' worth of records, you can see trends that you wouldn't have been able to see. Automotive has been doing this for a long time to track quality issues associated with global suppliers.

The other thing I've found, being a security expert, is the fact that organizations oftentimes insist on picking the most complex, difficult, and most secure technology that is offered at that time. Really, that problems becomes extremely difficult then to implement those technologies. Half implementation is almost worse than no implementation at all. As has been said here, if people go half one way and half the other, you're really not going to kind of get the adoption that you want.

So it's really important that you find a simple and secure method for implementation of e-prescribing. Those types of methods are certainly found in other areas. Again, they're found in manufacturing and automotive, but they're certainly found in other areas, also. For example, Web banking that we do right now. The New York Stock Exchange does all of its transactions electronically and they don't seem to be worried about the fact that people could steal trillions of dollars of information.

So what are kind of the security methodologies, at least, that we have seen work in an industry with large constituents that don't necessarily trust each other? The first thing is, a secure authentication is extremely important, so something that authenticates the user. But you don't have to go to thinks like PKI, you don't have to go to things like issued Smart Cards. There are other authentication mechanisms. Again, I do Web banking with an ID and a password, some additional questions. The world does that. It seems to be good enough for the guy from the FDIC, so I would assume it might be good enough for this.

Also, the idea that there are identity providers that are already out there. Large hospital systems, large pharmacy organizations that manage IDs today that can vouch for the identity of an individual.

In addition, the implementation of some sort of trusted broker is definitely something that we have seen. If you have organizations that are working with each other—for example, a doctor who's working with the pharmacy—they could collude, and even in an electronic system they could find a way that nobody might see that. If you put someone in the middle of the transaction, some type of independent party who kind of monitors it, it's much more difficult to collude between organizations.

Then, last off, you really need both policy and oversight that can be implemented in a consistent manner. Simplicity is the most important thing here. If it's not simple, it won't be adopted.

So in conclusion, I really think that the success of any system that we have is really about adoption. Adoption is the most important thing that we've seen in the automotive industry, that we've seen in health care industries in general. It has to be cost effective and secure. We certainly believe that any move toward an electronic system is much superior to the paper-based system that we have.

So, I thank you for the opportunity to testify.

Senator WHITEHOUSE. I thank you, Mr. Miller.

[The prepared statement of Mr. Miller appears in the appendix.]

Senator WHITEHOUSE. Mr. Podgurski.

STATEMENT OF MIKE A. PODGURSKI, R.Ph., VICE PRESIDENT PHARMACY SERVICES, RITE AID CORPORATION CAMP HILL, PENNSYLVANIA

Mr. PODGURSKI. Good morning, Senator Whitehouse. I am Mike Podgurski. I'm vice president of Pharmacy Services for the Rite Aid Corporation. I'm a graduate of West Virginia University's School of Pharmacy, and I've been involved with many aspects of the practice of pharmacy for 35 years. We thank you for this opportunity to provide testimony today for this important hearing regarding the electronic prescribing of controlled substances.

Rite Aid, which is based in Camp Hill, Pennsylvania, is one of the Nation's largest retail pharmacy chains. We operate approximately 5,100 pharmacies in 31 States and the District of Columbia.

Rite Aid has been involved for many years in the development of the current electronic prescribing infrastructure. For example, I was involved in the development of Rite Aid's own e-prescribing system in 1998. Our company has also been very actively involved in the development of the Pharmacy Health Information Exchange operated by Sure Scripts. This system currently serves as a secure platform for the transmission of all the e-prescriptions which Rite Aid receives today.

Rite Aid strongly supports the ability of prescribers to send, and retail pharmacies to receive, e-prescriptions for controlled substances in Schedules II through V. We especially appreciate your support for this initiative, Senator Whitehouse, as you recently expressed in a colloquy with other Senators.

The health care system needs to increase the number of prescriptions that are transmitted electronically. About 3.2 billion prescriptions are filled in the United States each year. The majority of these prescriptions are still written by prescribers on small, 3 x 5-inch pieces of paper, handed to the patient, and brought by the patient or caregiver to the pharmacist for dispensing.

In this day and age, the health care system can, and must, do better in using technology in transmitting all prescriptions to pharmacies, including controlled substances. Each of our 5,100 pharmacies across the United States is currently able to receive e-prescriptions. These include new prescription orders, as well as approvals to refill existing prescriptions.

These electronic transmissions have greatly enhanced the efficiency of our pharmacists. This allows pharmacists additional time to interact with patients and lessens the time the pharmacist spends on the phone trying to obtain a refill authorization or clarifying prescription orders with the prescribers' offices.

The frequency with which prescribers are sending prescriptions electronically is increasing, but we need to encourage more prescribers to transmit new prescriptions and we need to permit and encourage those who do e-prescribe today to send all prescriptions electronically.

There are multiple health care and efficiency benefits to e-prescribing, including those prescriptions for controlled substances. First, e-prescriptions are easier for the pharmacist to read, which may reduce the chances that errors might be made in the filling of these prescriptions. It also reduces the likelihood that a pharmacist may make a transcription error when taking a prescriber's oral prescription order over the telephone.

Second, before the prescriber sends an e-prescription to the pharmacy of the patient's choosing, the prescriber is able to perform an initial drug interaction or adverse reaction review to make sure that the new drug being prescribed does not conflict with a prescription drug that the patient is already taking.

Third, e-prescribing provides significant convenience for patients. Using this system, prescribers can transmit prescriptions so that they are ready for pick-up when the patient arrives at the pharmacy. However, because controlled substance prescriptions cannot be transmitted this way, the patient convenience and benefits of e-prescribing are significantly reduced.

We understand and recognize the concerns of law enforcement agencies, including the Drug Enforcement Administration, about the need to assure that e-prescribing does not result in additional diversion of controlled substances.

Rite Aid takes seriously our responsibilities to appropriately dispense and account for controlled substances we purchase and provide to our patients. However, we believe that e-prescribing of controlled substances will reduce diversion and abuse of controlled substances because of the significant security features incorporated into the system.

An increase in the electronic transmission of prescriptions may also help reduce the need for paper prescription pads. These paper prescription pads are more subject to theft and forgery. In addition, pharmacists make every effort to verify the authenticity of the per-

son communicating oral prescriptions for controlled substances. However, the secure electronic transmission of controlled substance prescriptions may reduce the incidence of phony prescriptions being called into the pharmacy.

In conclusion, we look forward to working with the Congress and the DEA to ensure that workable regulations are developed that would allow for the e-prescribing of controlled substances. We believe this would enhance medical benefits to patients, increase efficiencies in the prescribing and dispensing of controlled substances, and reduce—not increase—the potential for diversion and abuse of these substances.

I look forward to answering any questions you may have. Thank you.

[The prepared statement of Mr. Podgurski appears in the appendix.]

Senator WHITEHOUSE. Well, thank you all for your testimony and for your expertise and interest in this area.

The first question I'd like to ask is for Mr. Hutchinson and Mr. Miller, and you can go back and forth in any way that you're comfortable with. But you have handled this as a technical question in this and in other fields. If DEA were to come to you and to say, here's our problem: we want to make sure people can't cut into the system and divert prescription drugs for unauthorized purposes, what do we need to do to accomplish that in the most sensible, thoughtful, efficient, and effective way, what would you tell them? And particularly with respect to you, Mr. Hutchinson. Would you tell them, use our system? If they said, we're going to hand over to you this question of controlled substances, would you feel that you needed to add additional safeguards for that into the Sure Script system as it now operates?

Mr. HUTCHINSON. It's a very good question, sir. I think the response I would give, is that we feel that the systems and the networks that are in place today in this country to process prescriptions electronically are sufficient to process controlled substances. In fact, if the concern is a prosecution traceability/trackability, we've even offered up that we could allow prescriptions to go electronically to the pharmacies, but yet also allow the DEA to have a copy of all controlled substances in a real-time mode where they could track themselves the prescriptions that would go in an electronic format.

I think, from an auditability and traceability standpoint, it actually increases in a very real-time mode their ability to track controlled substances and the use thereof. We have over 140 different software systems that are on the network, so the physicians and pharmacies are able to choose their choice of software. They are the ones that register these users on the network and do the authentication directly of their own user base onto the network. These are licensed pharmacies. These are, as I mentioned in my testimony, not Internet pharmacies. These are not rogue pharmacies. So, those systems and those pharmacies are not on the network, and will not be on the network.

Senator WHITEHOUSE. In our research, my wonderful staff found testimony from Mr. Ratliff of your organization at a previous hearing in which he said, "We have maintained the confidentiality and

integrity of these transmissions," the e-prescribing transmissions, "for the prescriptions that can be transmitted electronically and have had no instances of tampering." He went on to say, "We believe that the electronic prescribing process greatly improves security for the prescribing of all prescriptions in comparison to today's written and oral processes for prescription information."

Now, this is from some time ago. Is it still valid that you can assert that the Sure Scripts system has not been hacked and tampered with and that you're confident in its integrity?

Mr. HUTCHINSON. It's absolutely valid. It was valid then, it's valid today. We've been working on this very issue for several years and it will maintain to be valid in the future.

Senator WHITEHOUSE. So your answer to the question of, what do you tell DEA, is get off the dime and use us?

Mr. HUTCHINSON. Absolutely.

Senator WHITEHOUSE. Mr. Miller.

Mr. MILLER. I think our answer to DEA would be very similar to Mr. Hutchinson's answer. There is no single solution. You need to do something. Any electronic e-prescribing methodology is going to be more secure than a paper-based system that we see today.

Senator WHITEHOUSE. Any? Repeat that.

Mr. MILLER. Any. Any based will be more secure than what we have today. As I said before—

Senator WHITEHOUSE. Can I ask you to repeat that just one more time for effect?

[Laughter.]

Mr. MILLER. Sure. Any e-prescribed based system will be more secure than the paper-based system that is currently used today.

Senator WHITEHOUSE. OK. Thank you.

Mr. MILLER. It is more trackable, it is more secure. It is definitely used in other industries. Again, if this was the leading edge thing and no one had ever even though of doing electronic transactions over the Internet, then perhaps it would be, we need to do a pilot and kind of try, maybe spend 3 years figuring it out. But we all trade on the Internet, we all do banking on the Internet. I guarantee you, your health records are going back and forth on the Internet now anyway, even if you're not e-prescribing. So the first answer is, really move forward with something.

The second thing, though, that is really important, is in reality, many of the doctors that you're talking about are not sophisticated computer users. If you pick a system that is difficult for them to implement, they won't. The doctors that I know are much more interested in patient care than they are about the latest version of Windows, so you need to find methodologies and systems that are more simple. Does that mean that it may be a little less secure? Possibly. But again, it is definitely more secure than the current paper-based system that we have today.

Senator WHITEHOUSE. Now, you say this from the position of also being a Department of Justice vendor, are you not?

Mr. MILLER. Yes. Covisint also provides electronic identity transaction for a law enforcement sharing program that basically allows information related to terrorist activity to be shared both with Federal and local law enforcement. That, today, is done—

Senator WHITEHOUSE. That's fairly highly classified stuff that you don't want people floating in and out of.

Mr. MILLER. It is. It is definitely highly secure stuff that you don't want people to be able to access. That information is being transmitted today in a secure manner.

Senator WHITEHOUSE. Without PKI technology?

Mr. MILLER. Without PKI technology. As a matter of fact, the authentication mechanism used by the FBI in their system is also currently without PKI technology, although moving to it. So, there are cases where the utilization of other security technologies certainly work, again, in banking, law enforcement. Is it possible that somebody can use this to perhaps find a way to get around the system? Yes, anything is possible.

But again, if you look at the system we have today, which is little pieces of paper that are transmitted back and forth, it certainly is more secure to be able to do it in encrypted and tracked technology. I think that's really the big deal. In electronic communication, I can watch all that happens. People who are watched have a tendency to not want to break the law. It's a lot easier if you're not watched.

Senator WHITEHOUSE. And you can also, because the electronic information can be easily, cheaply, quickly, and effectively aggregated, you can very quickly detect patterns that are inconsistent with customer use and might indicate something is wrong so that you can make a proactive inquiry, correct? I mean, you can set up flags that go up and various times.

Mr. MILLER. Right. Right. That's absolutely true. Not only can you track very large patterns that you couldn't do, so you can take a look at a doctor who consistently is over-prescribing a medication over years of time, you also have the ability to set up real-time flags. So, for example, if some sort of bad guy is going to steal Oxycontin, he's not going to steal 11 tablets, he's going to steal a million of them. Well, no doctor prescribes a million tablets. I mean, you would see that immediately. It would be very easy for you to be able to identify the event that occurred and actually, you know, in many cases stop the event before the transaction is completed. I mean, that's how fast the electronic capability is.

Mr. HUTCHINSON. And imagine just the value of taking the prescription out of the patient's hands and being between the two providers, between the physician and the pharmacist to avoid that kind of opportunity for fraud.

Senator WHITEHOUSE. So the Drug Enforcement Administration, as we all know, is a division of the Department of Justice. So if I were to bring this question up with the new Attorney General, Attorney General Mukasey, I could safely report to him that this important question that is being wrestled with by his own Drug Enforcement Administration has already been conclusively and satisfactorily answered by other divisions of his very organization?

Mr. MILLER. Absolutely.

Senator WHITEHOUSE. I think I might make that point.

[Laughter.]

The other thing I wanted to get into—I don't know. We're a little bit into the technical piece of this, Mr. Podgurski, and I'm not sure

if that's where you're comfortable. But if you wanted to add something to this, I'd be delighted to hear from you as well.

Mr. PODGURSKI. No. I was just going to say, on the security angle and the way Sure Scripts has the validation and verification process in place, that I wasn't aware of any breaches. I think it's the most secure system that we have for e-prescriptions out there.

Senator WHITEHOUSE. OK.

The other place I'd like to go with my questioning is to try to put a little bit more of a kind of practical and human face on some of the opportunity costs that we're missing by not being here and by not being up to speed with e-prescribing on controlled substances.

You can probably think of others, and if you do please remind me, but my notes from your testimony today fall basically into four categories. One, is patient safety, with sort of the subcategories of accuracy of the prescription and drug interaction alerts that can be prompted electronically. The second would be compliance with prescription regimes, the ability to track a little bit better what's going on.

The third would be administrative efficiency within the system so that costs are reduced and people don't have to pay as much for a prescription because the pharmacy industry is able to deliver it more efficiently. The fourth would be data gathering, not just from a fraud and abuse prevention point of view, but also from a public health point of view. There are four witnesses and there are four of those points, so what I would like to do is basically target each of you with one of them.

Ms. Adams, if I could start with you on the issue of compliance with prescription regimes. What is the state of knowledge about how compliant people are with prescription regimes? How serious an issue is the non-compliance, what are its effects, and how does e-prescribing help on the compliance issue?

Ms. ADAMS. It's a serious issue in that we know that upwards of 30 percent of all prescriptions are never filled, than if that patient returns back—I mean, even for non-controlled substances, it's a problem. If the patient returns back and their blood pressure remains high, they may get an increased dosage. Maybe this time they start taking that prescription when they never were taking the original prescription but the prescriber thought they were. So the percentage is very high, surprisingly high.

Senator WHITEHOUSE. When we're asked by our doctors if we actually picked up the prescription?

Ms. ADAMS. Oftentimes we are not. That assumption has been made. In fact, I think it's just now becoming new knowledge to providers that their patients aren't taking their prescriptions. We're finding that out through what? Electronic prescribing, because we now have records of whether or not patients pick up those prescriptions. The pharmacy never knows if a doctor writes something on a piece of paper and the patient never brings it to them. So, we have that capability of discovering something new.

The point that I was making earlier about the advancement of innovation, this is exactly what we're talking about here, when that prescriber can know that that patient never picked it up. There are other issues around compliance. It's not just that somebody decided not to do it. It could be that they don't have the

money to pay for that prescription. But they'll suffer the consequences, and so will society down the line. We'll still pay for that patient's condition, but only after they've had their heart attack because they're not taking their beta blocker or something of that nature.

So, it once again contributes to hospitalizations, contributes to visits to the doctor's office, it contributes to the overall cost structure and the harm structure that goes on because the physician is not able to have that discussion with the patient: "Gee, I see that you didn't pick up the prescription." "Well, you know what? I didn't have transportation this week." "Oh, OK. Well, we're going to solve that problem with your case manager." We won't have that information otherwise. That is afforded to us through electronic prescribing.

Senator WHITEHOUSE. So it's not just not picking up the prescription the first time when you go, have a single prescription. It also applies to people who have chronic illnesses and require consistent prescription drug support and the doctor can get a flag when a regularly collected medicine is not picked up and can intervene at that point.

Ms. ADAMS. Correct.

Senator WHITEHOUSE. And that person is totally missed right now by the health care system.

Ms. ADAMS. So we'll know if that patient that needs that for correct management of their chronic illness isn't taking enough of that drug, because by now had they been taking the prescription as prescribed, it should be renewed. We wouldn't know that otherwise. Through the electronic system, we have information that, now it's time for that patient to be renewing. If they're not, we need to be connecting with them to find out why they're not getting their next scheduled renewal of that drug.

Senator WHITEHOUSE. Valuable public health information.

Ms. ADAMS. Absolutely.

Senator WHITEHOUSE. Mr. Hutchinson, let me ask you about the safety questions of the accuracy of the transmission between Dr. Coburn deciding that this is the prescription he intends for the patient to take with what the pharmacist ends up reading and dispensing, and also with respect to the drug interaction. How significant are those, from a public health point of view? What are the costs? Put kind of a human and practical face on those, if you would.

Mr. HUTCHINSON. I'll give you a bonus, because I'll add a little bit more color to the issue around adherence as well.

Senator WHITEHOUSE. Please.

Mr. HUTCHINSON. Something that should be pointed out, is that Walgreen's and IMS just concluded a study that looked at physicians prior to adopting e-prescribing and physicians post e-prescribing. One of the major concerns the pharmacy industry had is restocking charges. Am I going to get all these prescriptions electronically that patients aren't going to come in and pick up, and now I'm having to restock these prescriptions on the shelves?

In fact, they found the exact opposite. Once they go to electronic prescribing to patients, they dispensed 11 percent more prescriptions on a per-physician basis once it goes to e-prescribing, which

means that patients are more compliant with physicians' orders once they know that the drugs have been sent electronically. That goes directly to patient safety as well, because if the patients are not taking their medications as prescribed by their physicians, then in fact what happens is they end up back in the physician's office, or in an emergency room, or in a hospitalization.

There's a wonderful, wonderful study that's out there now—we have plenty of studies on this topic, by the way. We don't need any more pilots or any more studies. The Henry Ford Medical Center just published some recent results that showed that they were able to cut their hospitalizations and their emergency room visits in half, and one-third of those cuts in those visits were directly attributable to electronic prescribing and the avoidance of drug interactions associated with that, because they're able to track the original order that a physician was going to prescribe, and then, post drug interaction, the change of that medication to a safer medication according to that drug interaction alert that was given.

Senator WHITEHOUSE. And their result was—repeat that for me. A third of—

Mr. HUTCHINSON. They cut their hospitalizations due to adverse drug events, and their ER visits due to adverse drug events, in half. They attributed 33 percent of those cuts directly to the fact that they were electronically prescribed medications.

Senator WHITEHOUSE. So of the 530,000 adverse drug events that Mr. Trenkle referred to earlier in his testimony, a sixth of that would be eliminated just by e-prescribing alone without further—

Mr. HUTCHINSON. That's exactly right. A percentage of those—

Senator WHITEHOUSE. Three thousand folks.

Mr. HUTCHINSON [continuing]. Would be direct to hospitalization or admission to hospitals, and a percentage of those would also be attributed to potentially an emergency room visit due to that drug interaction, and they were able to cut, due to the implementation of electronic prescribing, those hospitalizations due to ADEs, and emergency room visits due to ADEs, in half.

Senator WHITEHOUSE. And what can you tell us, kind of from a practical point of view, about the accuracy issue, about the extent to which errors occur because, famously, physicians' handwriting is illegible, decimals are misplaced, and so forth? Is there any information on how big a role that simple issue of inaccuracy and illegibility impacts on Americans' health?

Mr. HUTCHINSON. Yes. There are a lot of studies that relate to this very matter. The practical example that I will give you is, so long as it is actually truly electronically prescribed as defined by the standards that HHS has established in the Medicare Modernization Act, then you will see a significant improvement in that legibility, because we need to eliminate the fax as well. You need duplication of entry into the computer. Whatever is entered into the physician's computer is exactly what shows up in the pharmacy's computer.

Why that is important, is even in a faxed prescription environment, sometimes a milligrams of 1.0 may be misread or misentered as 10. When it comes from application to application, the computer does not misintepret the decimal symbol, so we actually have prop-

er and accurate prescriptions. Whatever the physician orders is exactly what the pharmacy dispenses.

Senator WHITEHOUSE. And how often does an inaccuracy result in a missed prescription or a health care problem for people in America? Is that a rare and unusual problem? Is it a significant problem?

Mr. HUTCHINSON. It's a significant problem. I don't have a number at my fingertips to be able to give you today.

Senator WHITEHOUSE. If you find one, could I make that a question for the record so you could get back to us before the hearing record concludes?

Mr. HUTCHINSON. I will, yes.

Senator WHITEHOUSE. Thank you.

[The information appears in the appendix.]

Senator WHITEHOUSE. Mr. Miller, my question for you has to do with the data gathering and the sort of public health aspect of it. I guess, beyond what we talked about earlier, do you see public health value from being able to sort of track, ultimately even around the country, where a prescription for a particular type of drug is, for instance, suddenly ballooning or where associations can be developed between a particular drug and a condition that may emerge weeks later after the use? Is there public health value here to this?

Mr. MILLER. Absolutely. So if you take a look at a parallel effort, which is really the ability to do electronic health records, those electronic health records, along with a robust e-prescribing program, would allow you to see certain drug interactions, not only with other drugs, but drug interactions in general with patients that you may not have seen before. So not only do you see that Oxycontin is being prescribed, but what you do see, is you see the number of hospital visits, for example, that occur. You can only do that if you can marry those two electronic transactions together as opposed to paper-based.

Senator WHITEHOUSE. If you have to do it with paper, you'd go—

Mr. MILLER. Well, you'd employ a lot of people, I suppose.

Senator WHITEHOUSE. At vast expense.

Mr. MILLER. The other thing that is interesting, and it's an interesting parallel, is that what we're seeing in health care in general is the old days of me going to the same physician all the time, where, to be honest, the reason why there weren't drug interactions and he knew what I was taking, is he's the only person who ever prescribes me anything, and by the way, probably going to the same pharmacist down the road. Those days are gone. They're either gone because you travel so much that you go lots of places, or more tragically, that you don't have health insurance, so what you do is you go to free clinics and you go to the ER, where, to be honest, that doctor basically has absolutely no idea what you have been doing, or haven't been doing.

Senator WHITEHOUSE. Or you're chronically ill and have five or six specialists all working on you at once.

Mr. MILLER. Or you're chronically ill and you have fix or six specialists. Those things are the things, really, that electronic prescribing allows the doctor to be able to understand all the prescriptions that you are currently taking. So I actually have a personal

experience, where my mother went into the hospital last summer and she couldn't remember whether or not she had filled her prescription for her heart medication.

The ER doctor said, I need to know, because if you have filled it and taken it I can't give you this drug, and if you haven't, then I need to give you this drug. Well, she couldn't remember. Without electronic prescriptions, there really was no way to tell. It was kind of more of a crap shoot. So, those are, I think, some of the things that are just really important with that.

Senator WHITEHOUSE. The last point was the internal efficiency. Nobody could be more knowledgeable about that than you, Mr. Podgurski. Could you kind of quantify, from an industry point of view, what benefits do you see if we move from a paper system and are able to eliminate it and go fully to an e-prescribing system in terms of your ability to make this transaction more efficient and reduce costs for American consumers?

Mr. PODGURSKI. Well, the thing is, with the efficiencies, these prescriptions come directly into the computer so you don't have to do a data entry. They still go through adverse drug reactions at the pharmacy, but they automatically come into the system and print a hard copy, which is still required, and are identified as e-Rxs. They also have an electronic signature on them that makes them valid for the secure purposes.

There's a pharmacist shortage across this Nation. Many pharmacists work in different pharmacies today. No longer will you see many of the same people continually only working in one store. Those individuals used to be able to identify a doctor's signature, a doctor's nurse calling in. Those days have gone by the wayside.

E-prescriptions would bring an authenticity to that. Pharmacists still have a duty to make sure that the prescription is valid, and the State Boards of Pharmacy have given them the authority to use their professional judgment in dispensing medications. So looking at, if it's an out-of-the-area prescriber, a new patient that's out of the area, those things won't go by the wayside when looking at the authenticity, even if it's an electronic prescription. They still have a duty to verify those.

Senator WHITEHOUSE. Good. Well, this hearing was scheduled to end at noon and we've come to the noon hour. If anybody has a closing point of any kind they would like to make, I'm not in any particular rush and I'd welcome any final point, if anybody has something they'd like to make.

Ms. ADAMS. Senator Whitehouse, I'd just like to add one statistic to that—

Senator WHITEHOUSE. Please.

Ms. ADAMS [continuing]. That Mr. Miller was referencing, that notion of, in this day and age, multiple providers. Studies have shown that Medicare beneficiaries see anywhere from 1.5 to 13.8 unique providers each year, 13.8 unique providers, none of whom are able to talk to each other if everybody is using a paper-based system. The issue is serious.

Senator WHITEHOUSE. So the electronic e-prescribing system really becomes the safety net under that circumstance with respect to their prescriptions.

Ms. ADAMS. That's right. You're not the only doctor they're seeing, the only pharmacy that's filling your prescriptions; 13.8 doctors are making prescriptions here, and the drug interaction potential is horrendous.

Senator WHITEHOUSE. Well, thank you very much. I will call this hearing very shortly to its end. We will leave the record of the hearing open for 7 days, so the questions that have been asked for the record, we'd like to have within 7 days, with the exception, in DEA's case, of the 60 days that we granted you. But the record of this particular hearing will close then.

I want to thank all of you for your travel here, for your very helpful and thoughtful testimony. I know you've come a considerable distance and you all have very busy lives. It has been very helpful to me, and I hope to my colleagues, to have you here. I think it will make a difference if we can push through this problem.

I would like to, I guess, close with one observation, to put this into some context as to why I called this hearing and why I think it's so important. I also serve on the Budget Committee with Senator Conrad, who is a brilliant chairman of the Budget Committee and a very able and sensible person, certainly not anyone who is any kind of an hysteric.

The information that we have received in the Budget Committee, and the conclusions that he, I, and others have drawn about them, show that we are headed for a real potential disaster in our health care system. There is what he has described as a tsunami of cost coming at us in the American health care system. The people who will receive that medical care have already been born. They are here. We can't do anything about their presence. Time makes them older, second by second. We can't do anything about the passage of time.

Aging human beings require more health care services than younger ones. That is a fact of life. I don't know that we can do much about that. Unless we can do something about the efficiency with which we deliver that health care to those people, the combination of those factors will make our already wasteful health care system unaffordable. If our health care system becomes unaffordable, then the only place we have to go is to cut people off of it: seniors, working families, children. That is not acceptable.

The alternative, the only alternative, is to get ahead now while we have the time to make it work and build the infrastructure that can make our health care system sufficiently efficient to continue to serve Americans the way they expect, to actually improve the health care service that America gets, but to do it at a cost that America can afford. It is the electronic health infrastructure that is our best avenue to accomplishing that goal.

Now, this is kind of a macro point. It's probably going to take 10, 15, 20 years for all this to play out. But as time goes by and we lose the opportunity to get in ahead and build this into place, the potential costs on the back end to people who will pay the price in lowered health care services is a very, very real one, and a very human one, and a very tragic one. So, 3 years is more than we have to wait on this. We have got to get going now, because e-prescribing is a gateway to this. Many of you have said it.

I think it's really important not just from a diversion point of view, not just from a wow-isn't-this-a-wonderful-gizmo-it's-going-to-make-people-get-their-prescriptions-more-efficiently point of view, but from a point of view of where our American health care system goes. This has been a really important point for us to tackle, so your effort in coming here is much, much appreciated.

This was my first hearing—I'm a new Senator—the first one that I've called and held. So I want to also, on the record, express my appreciation to the brilliant staffers: Jordana Levinson, my health care staffer, and Sam Goodstein, my Judiciary staffer who have prepared me for this and worked with all of you to get here today. So, with my thanks to them and a reminder that 7 days is when the hearing record will close, we are adjourned.

[Whereupon, at 12:09 p.m. the hearing was adjourned.]

[Questions and answers and submissions for the record follow.]

QUESTIONS AND ANSWERS
Questions for DEA Director Rannazzisi

1. Does the DEA currently use any technology to securely transmit information in the healthcare community?

2. Why doesn't the DEA use the existing platform for electronic prescriptions?

3. Why has the DEA still not promulgated the necessary regulations to allow for e-prescribing of controlled substances? Does the OMB have to sign onto these regulations? If so, are they the source of the hold-up? If not, is there any other agency in the federal government that is delaying you?

4. My staff has informed me that the DEA has posted as its policy that e-prescriptions for controlled substances are invalid. However, my staff has also informed me that the DEA has also circulated a 2002 letter which states that the DEA policy is to treat e-prescriptions of controlled substances as oral orders, i.e., that they can be valid in some circumstances.
    a. For the record, which is the correct policy?
    b. What caused this confusion?

5. Does the DEA wish to continue with the regulation process, or would you be open to Congress stepping in with a legislative fix?

6. DEA's semi annual regulations agenda indicates that a NPRM for E-prescription for controlled substances is set for June '08, comment period ending September '08.
    a. Is this correct?
    b. Although this agenda was published 7 days after the hearing, presumably you were aware of its contents in advance. Why did you not simply inform the committee of this upcoming NPRM when you were pressed for a timeline?

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Follow-up Questions of Senator Tom Coburn, M.D.
Hearing: *"Electronic Prescribing of Controlled Substances: Addressing Health Care and Law Enforcement Priorities"*
United States Senate Committee on the Judiciary
December 4, 2007

Joseph T. Rannazzisi, Deputy Assistant Administrator, Drug Enforcement Administration:

1. The DEA is responsible for promulgating regulations to allow e-prescribing of controlled substances. What, or who, specifically, has prevented the DEA from getting this done?

2. Other than the 3 characteristics you mentioned as critical to any e-prescription system, please list *specific* safeguards that must exist to ensure both those characteristics and a system that meets the law enforcement needs of the DEA.

3. You testified that the DEA began studying e-prescriptions in 1999, almost a decade ago. How much longer do you estimate it will take to promulgate these regulations?

4. What have you done to ensure that these regulations are developed as quickly as possible?

5. What can Congress do to help the DEA issue these regulations as quickly as possible?

53359.002

U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D C 20530

February 1, 2008

The Honorable Patrick J. Leahy
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Please find enclosed a response to questions arising from the appearance of Drug Enforcement Administration Deputy Assistant Administrator Joseph Rannazzisi before the Committee on December 4, 2007, at a hearing entitled "Electronic Prescribing of Controlled Substances: Addressing Health Care and Law Enforcement Priorities."

We hope that this information is of assistance to the Committee. Please do not hesitate to call upon us if we may be of additional assistance. The Office of Management and Budget has advised us that from the perspective of the Administration's program, there is no objection to submission of this letter.

Sincerely,

Brian A. Benczkowski
Principal Deputy Assistant Attorney General

Cc: The Honorable Arlen Specter
Ranking Member

**"Electronic Prescribing of Controlled Substances:
Addressing Health Care and Law Enforcement Priorities"**

December 4, 2007

**Questions for the Hearing Record
for
Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration**

QUESTION FROM SENATOR WHITEHOUSE:

1. **Please provide the best estimate on the time frame for issuance of a final rule by DEA establishing standards for electronic prescriptions for controlled substances.**

RESPONSE:

DEA recognizes the importance of establishing a rule to permit the responsible electronic prescribing of controlled substances (EPCS). During any rulemaking, multiple agencies have input into the process, which makes setting a hard timetable impractical.

DEA has provided the Department of Justice (DOJ) with a proposed rule regarding the electronic prescribing of controlled substances.

DEA is unable to accurately predict how long the DOJ review will last, but DEA does know with certainty:

1. The Office of Management and Budget (OMB) will review this Notice of Proposed Rulemaking (NPRM) pursuant to Executive Order 12866. OMB has 90 days in which to complete this review from the date that the rule is submitted.

2. Due to the complexity of this issue, the comment period is planned to be 90 days.

3. DEA cannot predict the number, nature, or complexity of the comments it may receive to the NPRM. Therefore, it is not possible-for DEA to predict the length of time needed to draft a Final Rule in which it will consider all comments received and finalize the regulations. Nor can DEA predict the time necessary for DOJ to review the rule once drafted.

4. The Office of Management and Budget will review this Final Rule pursuant to Executive Order 12866. OMB has 90 days in which to complete this review from the date that the rule is submitted.

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SUBMISSIONS FOR THE RECORD

AARP STATEMENT FOR THE RECORD ON

ELECTRONIC PRESCRIBING OF CONTROLLED SUBSTANCES:

ADDRESSING HEALTH CARE AND LAW ENFORCEMENT

PRIORITIES

SUBMITTED TO THE

SENATE JUDICIARY COMMITTEE

December 7, 2007

WASHINGTON, D. C.

For further information, contact:
Anna Schwamlein Howard
Federal Affairs Department
(202) 434-3770

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AARP is pleased that this Committee – and Congress as a whole – is advancing the issue of electronic prescribing. Rarely does Congress have the opportunity to improve the quality of the U.S. health care system and save taxpayer dollars at the same time. AARP supports the wide adoption of electronic prescribing and is pleased that last week the American Health Information Community (AHIC) recommended an e-prescribing mandate for the Medicare program.

In the U.S., over 3 billion prescriptions are written annually. Astoundingly, in today's modern age, most of these prescriptions are written on paper – non electronic – forms. Continuous reliance on the paper-based system exposes the U.S. health care system to excessive waste, costs, and erosion of quality health care. Moving from a paper-based system to a more efficient, electronic system of prescribing can improve the quality and efficiency of the U.S. health care system.

In 2006, the Institute of Medicine estimated that preventable medication errors result in approximately 7,000 deaths per year and cost the health care system $77 billion annually. Even more startling according to one study, medication errors alone account for more than 7 percent of total national health care expenditures—enough to cover a substantial portion of those lacking health insurance.[1] In its 2006 report, the IOM called on all physicians to adopt electronic prescribing by 2010 to address this problem. Unfortunately, recent studies indicate that despite the fact that physicians believe that e-prescribing will be good for medicine, only about one in ten actually use it on a regular basis.

[1] Krawlewski, J., Dowd, B., Drug Errors in Medical Practices: It's Dangerous Out There, 2005, University of Minnesota, Division of Health Services Research and Policy: Minneapolis.

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Electronic prescribing, can improve the quality of health care for millions of Americans by:

- Reducing errors resulting from illegible handwriting;
- Reducing transcription errors;
- Providing prescribers with real time safety alerts on drug-to-drug interactions, duplicate therapies, or information on a patient's allergies;
- Providing information on appropriate drug usage (such as dosage amounts);
- Enabling physicians' access to key information such as formularies, patient's choice of prescription drugs; and clinical and affordability data (like co-pays);
- Creating instant electronic connectivity to the health plan, provider, pharmacist, and Pharmacy Benefit Manager providing a system of checks and balances to ensure proper prescribing; and
- Enabling effective prescribing by physicians to choose the most appropriate drug to treat an illness or disease.

Paper prescriptions are an anachronism. According to one report, pharmacists make more than 150 million calls to physicians each year to discuss possible errors or clarify prescriptions. In addition, paper prescriptions must be re-entered by hand at the pharmacy. This needlessly takes valuable time – time that a sick patient may not have to wait for the prescription to be processed, and time that the pharmacist could better use to more efficiently fill prescriptions. Refills can also be handled more efficiently with e-prescribing – according to one study, refill request times can decrease from an average of 15 minutes using paper prescriptions to 3 minutes using electronic prescribing.[2]

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[2] Statement of the Medical Group Management Association, Electronic Prescribing of Controlled Substances: Practitioner Perspective Panel, (Drug Enforcement Administration, July 11 2006).

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Moreover, paper prescriptions are all too easy to forge. An unscrupulous actor can easily falsify a prescription, turning one refill into ten refills, with the physician having little way of knowing the forgery occurred. This can be particularly problematic for controlled substances. Prescription pads can be stolen, copied, and forged. E-prescribing can help address many of these forgeries. In addition, electronic prescribing can help determine whether an individual is receiving a controlled substance through more than one provider.

Other global industries rely heavily on electronic records every day. Imagine what the worldwide banking system would look like if paper checks were required for every transaction. Millions of dollars are electronically moved every day in a safe, secure environment – a practice that is safer and even more secure than if paper checks were required.

AARP understands that some may be hesitant to broaden e-prescribing to include controlled substances. However, electronic security measures should better ensure the safety and integrity of these prescriptions and increase the ease for greater oversight by law enforcement. We are confident that, if necessary, additional safeguards for the prescribing of controlled substances can be implemented quickly.

Conclusion

In today's modern, electronic age, the requirement of electronic prescribing is long overdue – whether for controlled or non-controlled substances. All stakeholders – both public and private -- should work together to ensure that electronic prescribing for all prescription drugs becomes a reality as quickly as possible. Electronic prescribing will save time and money, and most importantly, improve health care and save lives. AARP stands ready to work with you to make this happen.

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Senate Committee on the Judiciary Hearing: *Electronic Prescribing of Controlled Substances: Addressing Health Care and Law Enforcement Priorities*

Testimony of Laura L. Adams, President and CEO, Rhode Island Quality Institute

December 4, 2007

Chairman Leahy and Members of the Committee, thank you for the opportunity to appear before you today to testify on this issue of great importance to the quality and safety of health care delivery in this country.

My name is Laura Adams and I'm President and CEO of the Rhode Island Quality Institute, a not-for-profit organization founded six years ago by then RI Attorney General, now US Senator, Sheldon Whitehouse. This multi-stakeholder organization, comprised of hospitals, physicians, nurses, consumers, insurers, and employers has the singular mission of significantly improving the quality, safety and value of health care in RI.

I'm here today to respectfully request that the Committee take action to urge the Drug Enforcement Administration and the Department of Justice to promulgate regulations for e-prescribing of controlled substances that are technology neutral; that build on today's safe and secure e-prescribing infrastructure; and allow for future changes and growth in technology, privacy and security safeguards, and industry expansion.

I'm going to speak about the need for these new regulations from the perspective of our broad-based coalition working together to transform the health care system in the state of RI. The Quality Institute serves as Rhode Island's Regional Health Information Organization (RHIO) and we strongly believe in the value of health information technology as an essential element in any viable proposal for addressing the problems that plague our health care system. It's our goal to bring the delivery of health care in our state out of the paper-based system, which we recognize as a root cause of significant waste and harm.

But in order for the people of our state and our nation to realize the promise of health information technology, their providers have to adopt it and use it. Our job in RI is to work diligently to lower barriers to adoption. Our Clinical IT Leadership Committee, a group of some of the most competent and

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respected thought-leader physicians in Rhode Island has identified the inability to electronically prescribe controlled substances as significant barrier to adoption. Some physicians on our Committee, who have devoting their scarce and valuable time to this work for more than three years, have cited this barrier as one of the primary reason that *they themselves* have not yet adopted electronic prescribing, even though they're sure of the benefits to patients, providers and those who pay for health care.

While approximately 12.5% of all prescribed drugs are controlled substances, perhaps a more significant number is the far higher percentage of patients that require the prescription of controlled substances in addition to medications that are permitted to be electronically prescribed. For example, in the very common situation where an elderly patient needs multiple medications to manage their chronic illnesses and some of the drugs are controlled, it makes it far more likely that a busy practitioner who has adopted electronic prescribing will default to the paper based system for *all* of the prescriptions for that patient rather than attempt to operate parallel systems in their complex office settings. Therefore, the inability to electronically prescribe controlled substances not only thwarts adoption in the first place, it suppresses the total number of electronic prescriptions written by those who providers who *have* adopted.

As I'm sure every member of the Committee knows, research has shown that medication errors are occurring at a disturbing rate in this country. With a staggering number of drugs on the market and more coming out all the time, it has become all but impossible for providers to rely on their memory for proper dosing, avoidance of drug-drug interactions and allergic reactions. I think David Eddy said it best when he said, "The complexity of modern medicine has exceeded the capacity of the unaided human mind".

Controlled substances include some of the most potent and potentially harmful drugs if given the wrong dose or with other drugs that result in untoward reactions. When a misplaced decimal point or a drug interaction can be catastrophic, these patients are effectively being denied access to a system that could save their lives. Patients who require controlled substances deserve the same opportunity for safer prescribing as all other patients.

Another problem of great concern to Emergency Room physicians in RI--that the electronic prescription of controlled substances could significantly reduce

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--is "doctor shopping" This is when patients with addictions or drug dependency problems go from physician to physician to obtain controlled substances. Electronic prescribing by Emergency Room physicians can help to identify patients who doctor shop much more quickly and efficiently than is now possible. Electronic prescribing creates an immediate electronic footprint or audit trail that is documented and time-stamped through each point in the process, from the prescribers' location to the pharmacy. These electronic audit trails show who accessed the prescription and when. If the medication is electronically prescribed, these automatic audit trails can expose doctor shopping, even if the patient pays cash.

This is not to say that electronic prescribing of controlled substances can address every instance of drug diversion. Electronic prescribing, however, can go a long way toward reducing the incidence of doctor shopping, reducing the rate of those who successfully forge prescriptions and/or alter the originals and increasing law enforcement's ability to prosecute these cases.

Electronic prescribing is far more secure than paper prescriptions. Paper prescription pads are often stolen or counterfeited, signatures are forged, and drug quantities are altered before the prescription is delivered to the pharmacy.

Electronic prescribing involves transmission of prescriptions over secure, private networks—not simply the Internet-- using industry-wide privacy and security standards to see to it that the transmissions are safe and secure.

I'm sure you've heard or will hear the testimony of experts in the area of secure transmission of data attesting to the safety and security of electronic prescribing. They'll speak to this in more depth.

But in short, the industry's ready. And the need has never been greater.

We're asking for your help to bring about the electronic prescribing of controlled substances and all of the benefits it affords consumers, providers and payers.

Thank you for this opportunity to come before you with this request.

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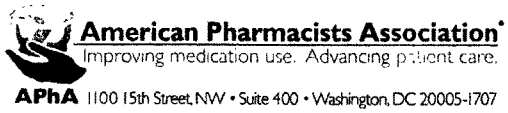
Statement of the
American Pharmacists Association

Submitted to the
United State Senate
Committee on the Judiciary

On

"Electronic Prescribing of Controlled Substances: Addressing Health Care and Law Enforcement Priorities"

December 4, 2007



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Statement of the American Pharmacists Association (APhA)
to the United States Senate
Committee on the Judiciary

Hearing on

"Electronic Prescribing of Controlled Substances:
Addressing Health Care and Law Enforcement Priorities"

The American Pharmacists Association (APhA) thanks the Committee for holding this important hearing and appreciates the opportunity to present pharmacists' perspectives on electronic prescribing of controlled substances. Advances in technology, the need for greater efficiencies in the health care system and the potential for improved patient safety have spurred a growing interest in electronic prescribing in recent years. If developed and implemented appropriately, electronic prescribing could improve patient safety while advancing the Drug Enforcement Administration's (DEA) goals of preventing illicit prescribing, doctor shopping, and drug diversion. Recognizing the potential, substantial benefit to the health care system, APhA supports efforts that would allow for the electronic prescribing and transmission of prescription orders for controlled substances.

APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings, and the military.

Despite its potential benefits, electronic prescribing and transmission of controlled substance prescription orders is currently prohibited. This obvious gap in the prescribing process denies the health care system — patients, pharmacists, and prescribers — the full benefits of electronic prescribing. While the absence of authority to electronically prescribe controlled substances does not prevent implementation of electronic prescribing in general, it does slow the adoption of a critical element of health information technology's (HIT) infrastructure. Allowing electronic prescribing of controlled substance would accelerate the rate of growth in electronic prescribing in general and help us meet our shared goal of wide adoption of HIT.

Benefits of Electronic Prescribing

There are many potential benefits to electronic prescribing and transmission of prescription orders. For example, an electronic system may provide pharmacists and physicians with improved access to patient electronic medical records and information about a patient's drug utilization history, possible drug interactions, insurance coverage, as well as lower-cost, therapeutically appropriate alternatives. By making this information available to both pharmacists and prescribers through secure, two-way electronic communications, electronic prescribing may facilitate more collaboration among pharmacists and prescribers. Collaboration may decrease the need for time-consuming phone calls between the pharmacist and the prescriber and between the pharmacist and the third party payer to address prescription order

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clarifications and authorizations — all of which delay patient access to medications. Electronic prescribing also has the potential to provide a safer medication delivery system by reducing medication errors caused by prescription inaccuracies and illegible handwritten prescriptions. It may also improve patient compliance by providing prescribers information on whether patients have picked up their prescriptions.

Electronic prescribing also has the potential to reduce the number of prescription forgeries by providing more reliable authentication of prescribers. Forging a prescription is relatively simple in the current paper-based environment despite the efforts of pharmacists to determine whether the prescriber and prescription is legitimate – is the prescriber who he says he is; does the prescriber have a legitimate DEA number; is the prescription authentic? As the "gate-keepers" for prescription medications, pharmacists evaluate each prescription they receive using their professional judgment, dispensing procedures and controls, and common sense. Pharmacists know the prescribers in their community, recognize the prescriber's signature, and can confirm the prescriber's DEA registration number. Pharmacists also know their patients. And when a questionable prescription is received, pharmacists question the prescription and contact the prescriber for verification or clarification. The same principles can and should apply to an electronic-based prescribing system. Implemented appropriately, using existing technology and security measures, prescription forgeries and diversion would be more difficult under an electronic prescribing system than in the current paper system.

The implementation of electronic prescribing may also have a tremendous impact on recordkeeping controls. Electronic prescribing enhances efficiencies and reduces opportunities for errors by creating an electronic record, allowing for digitally recorded interactions between the pharmacist and prescriber, and identifying the health care professionals involved in a patient's care as a prescription order moves though the prescribing and dispensing process. Electronic prescribing would reduce the administrative burden inherent in the current recordkeeping requirements of the Controlled Substances Act (CSA), provide tighter controls on the authenticity of records and turn around time to reconciliation, and perhaps most importantly, reduce time for patients to access necessary medications.

Implementation Recommendations

While pharmacists and all members of the health care and regulatory communities work together to ensure that the drug distribution system for all drugs is controlled and limits opportunities for drug abuse and diversion, controlled substances do possess an increased risk. To date, the DEA has attempted to mitigate this risk by placing rigorous requirements on the distribution of controlled substances. While we appreciate the Agency's goals, we believe technology exists to address its concerns and does not require the adoption of an entirely new system.

Other industries, such as the financial industry, apply safe and controlled electronic systems to stock trading, credit handling, and bank transactions every day; and electronic technology specific to health care and electronic prescribing is already in use that allows for the safe and secure transmission of sensitive information in a format that is compliant with the Health Insurance Portability and Accountability Act (HIPAA). These technologies provide for transmission security, integrity of the information transmitted, access control, and authentication.

In designing a comprehensive electronic prescribing system, all electronic prescriptions should be held to the same standard. While the risk for drug abuse or diversion may be greater with controlled substances, any electronic prescription – controlled substance or not – should be transmitted in a secure environment. This demands one seamless, integrated system for electronic prescribing, not two (one for controlled substances and another for non-controlled drugs). Absent a change, prescribers are left to work with two systems.

Additionally, a new system should be based on the electronic prescribing standards, including the National Council for Prescription Drug Program's (NCPDP) SCRIPT Standard, that are being established by HHS and the Centers for Medicare and Medicaid Services (CMS) as part of its efforts to develop electronic prescribing standards under the Medicare program. Finally, further efficiencies would be found in a new system that used the National Provider Identifier (NPI) as a provider identifier. The NPI, required for most in the health care system to comply with HIPAA, would be supplemented by the provider's DEA number when a controlled substance is prescribed.

Conclusion

APhA encourages the quick adoption of an electronic prescribing program for controlled substances that is designed to: facilitate pharmacists' ability to provide quality and efficient patient care; allow two-way communication between providers and pharmacists; be responsive to health care provider needs; be cost effective; prevent operational difficulties; and prevent new opportunities for error, diversion, or abuse. While, diversion and abuse concerns about controlled substances are valid, the need for heightened security and controls can be met with existing electronic prescribing technology and the adoption of one seamless, integrated system.

However, even the best designed electronic prescribing program requires adoption by prescribers and pharmacists. And adoption will depend on our collective ability to develop a cost-effective and user-friendly system that does not create new administrative burdens for pharmacists or prescribers. Congress, Federal Agencies, and the health care community have been working toward this goal for many years; now is the time to make it a reality.

Thank you for the opportunity to present the views of the nation's pharmacists.

CHCC
CORPORATE HEALTH CARE COALITION

Testimony Submitted for the Record

before the

United States Senate

Committee on the Judiciary

hearing on

"Electronic Prescribing of Controlled Substances: Addressing Health Care and Law Enforcement Priorities"

Tuesday, December 4, 2007

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The Corporate Health Care Coalition (CHCC) is pleased to provide testimony before the Senate Judiciary on e-prescribing of controlled substances. CHCC is comprised of large, multi-state, predominantly self-insured companies that operate health benefit plans for employees and their families as well as retirees. Our organization is distinguished by its focus on issues that are critical for employers who sponsor health benefit on a nationwide basis. Members of the CHCC have been in the forefront of efforts to ensure quality and cost-effective benefits since its inception.

To ensure quality and cost-effective health benefits it is crucial that the groundwork be laid to ensure the widespread adoption of health information technology. An important first step in laying that groundwork is the broad adoption of e-prescribing by prescribing clinicians. Controlled substances comprise approximately 12.5 percent of all prescriptions. Clinicians have been reluctant to invest in e-prescribing systems if they are unable to electronically prescribe controlled substances. In testimony delivered to the Committee for today's hearing, Laura L. Adams of the Rhode Island Quality Institute[1] notes that clinicians serving on the Institute's IT Clinical Leadership Committee "have cited the [inability to e-prescribed controlled substances as a] barrier and one of the primary reasons that they themselves have not yet adopted electronic prescribing, even though they're sure of the benefits to patients, providers and those who pay for health care."

The American Health Information Community (AHIC), an advisory group to the Health and Human Services secretary, recommended on November 28, 2007, that e-prescribing be made mandatory for all prescribing clinicians. As a condition to mandating e-prescribing, AHIC advised that all prescriptions be made electronically transmissible, including those for controlled substances. To date, the Drug Enforcement Administration (DEA) has not promulgated an e-prescribing regulation for controlled substances.

To encourage the adoption of e-prescribing technology and to lessen resistance to a mandate to e-prescribe, CHCC believes it is vital that both controlled and non-controlled substances be electronically transmissible and that prescribing clinicians be able to do so utilizing a single technology. Prescribing clinicians will resist e-prescribing if they are required to maintain two systems in their office – one for e-prescribing controlled substances and a second for e-prescribing non-controlled substances.

CHCC encourages the DEA to timely promulgate a workable, technology neutral e-prescribing regulation that builds on today's safe and secure e-prescribing infrastructure. Such a regulation will be an important step in encouraging the adoption of e-prescribing technology and, ultimately, the adoption of broader health information technology that will make health care safer and more efficient.

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[1] The Institute, a not-for-profit organization, is a multi-stakeholder organization, comprised of hospitals, physicians, nurses, consumers, insures, and employers with the mission of significantly improving the quality, safety and value of health care in Rhode Island.

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e-Prescribing Controlled Substances Coalition

Testimony Submitted for the Record

before the

United States Senate

Committee on the Judiciary

Hearing on

"Electronic Prescribing of Controlled Substances: Addressing Health Care and Law Enforcement Priorities"

Tuesday, December 4, 2007

e-Prescribing Controlled Substances Coalition

The e-Prescribing Controlled Substances Coalition is pleased to provide testimony before the Senate Judiciary Committee on e-prescribing of controlled substances. The Coalition is a large group of diverse stakeholders focused on promoting health care information technology, and electronic prescribing in particular. A list of Coalition members is provided in Attachment 1.

The Institute of Medicine (IOM) characterized high quality health care as being safe, effective, efficient and patient-centric. The IOM found that e-prescribing is essential to achieving these goals. Yet, despite the evidence that e-prescribing functions for all drugs, including controlled substances, in a safe and secure manner the Drug Enforcement Administration (DEA) has unnecessarily delayed issuing a workable regulation that would permit the e-prescribing of controlled substances.

Members of the Coalition, the U.S. Department of Health and Human Services and the Centers for Medicare and Medicaid Services have been working with the DEA for as long as five years to achieve e-prescribing of controlled and non-controlled substances. The American Health Information Community (AHIC), an advisory group to the HHS Secretary, recommended on November 28, 2007, that e-prescribing become mandatory. It noted that all prescriptions must be electronically transmissible and that DEA must take action to permit e-prescribing of controlled substances.

Therefore, the Coalition is urging that Congress act to allow e-prescribing of controlled substances. Omitting controlled substances from the prescribing process is denying patients and the health care system the full benefits that electronic prescribing offers. Just as importantly, this gap is depriving law enforcement of a valuable tool that will facilitate drug diversion control far better than today's labor-intensive, inefficient, and costly paper process.

Controlled substances comprise approximately 12.5 percent of all prescriptions, and permitting them to be e-prescribed will significantly increase provider use of electronic prescribing technology. Further, Coalition members believe that e-prescribing currently offers significantly more protection from illicit prescribing, doctor shopping and drug diversion than the current system of paper and verbal prescriptions. We continue to believe that the current e-prescribing process can address the concerns expressed by the DEA in numerous public meetings over the last several years. Greater detail on the safety and security of e-prescribing is provided in the Summary Questions, at Attachment 2, and the White Paper, at Attachment 3.

The undersigned members of the Coalition request that the Committee assist us in encouraging DEA to promulgate immediately a workable, technology neutral e-prescribing regulation that builds on today's safe and secure e-prescribing infrastructure.

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This will not only reduce diversion of controlled substances, but also encourage greater clinician adoption of e-prescribing and, ultimately, all facets of health information technology.

The country can no longer afford to have a segregated prescribing system. It is time for the e-prescribing and law enforcement communities to work together to harness all of the attendant benefits that health information technology can provide to the nation's health care system and the consumers it serves.

Attachments: 1. List of Coalition members
2. FAQs
3. White Paper

* * *

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Attachment 1

e-Prescribing Controlled Substances Coalition Members

Achieve Healthcare Information Technologies, LP
Aetna
American Benefits Council
American Health Care Association
America's Health Insurance Plans
American Medical Group Association
American Medical Informatics Association (AMIA)
American Nurses Association
Anthem Prescription Management
Arcadian Health
American Society of Consultant Pharmacists
American Society of Health-System Pharmacists
BlueCross BlueShield Association
ChartConnect, Inc.
CIGNA
Comcast
CVS Caremark
ePrescribe Florida
eRx Network, LLC
Express Scripts, Inc.
First Health Group Corporation
Giant of Maryland
Giant Foods
Healthcare Information and Management Systems Society
Healthcare Leadership Council
Humana, Inc.
Information Technology Industry Council
Kmart
Medco Health Solutions
MediMedia Information Technologies
MedPlus, Inc., a Quest Diagnostics Company
National Association of Chain Drug Stores
National Association of Health Underwriters
National Association of Manufacturers
National Council for Prescription Drug Programs, Inc.
Pharmaceutical Care Management Association
Prescription Solutions

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Prime Therapeutics, LLC
Rite Aid Corporation
RxHub, LLC
RxNT
Sage Software
Sears
Stop & Shop
SureScripts
The Kroger Company
U.S. Chamber of Commerce
Walgreens
Wal-Mart Stores, Inc.
WellPoint

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Attachment 2

e-Prescribing for Controlled Substances

ISSUE: Federal laws and regulations prohibiting controlled drug substances from being electronically prescribed are an impediment to the widespread adoption of electronic prescribing.

What is e-prescribing?

Electronic prescribing is a system that enables prescribing clinicians to securely deliver prescriptions via computer immediately from the point of care directly to a patient's pharmacy of choice. In addition to this prescription delivery function, e-prescribing improves patient safety through warnings to the prescribing clinician about adverse drug interactions and allergies, and previous medication history. It also addresses patient drug-regimen compliance issues by providing information on insurance eligibility status, prescription fill status notification and prescription renewal capability.

Is e-prescribing secure?

E-prescribing is far safer and more secure than paper prescriptions. Paper prescription pads are often stolen or counterfeited, signatures can be easily forged, and drug quantities can be manually altered before the prescription is delivered to the pharmacy.

E-prescribing is *not* simply sending a message to a pharmacy over the Internet. E-prescriptions are transmitted over secure, private networks, which employ industry-wide privacy and security standards to ensure the safety of patient data and its secure transmission. E-prescribing systems adhere to HIPAA privacy and security regulations with safeguards that include strong user authentication, firewalls, intrusion detection systems, security assessment, violation scanning and audit tools, periodic system risk assessments, data encryption and backup/disaster recovery capabilities. E-prescribing networks assure robustness of processes and performance through third-party oversight and accreditation (e.g., EHNAC).

Why are controlled substances not e-prescribed?

E-prescribing is not allowed for controlled substances at the present time under federal law and Drug Enforcement Administration (DEA) regulations. The DEA's reasons for not permitting e-prescribing of controlled substances are:

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- Only written prescriptions can reliably authenticate prescribers.

But e-prescribing does that as well. Prescribers must be credentialed, approved and also must use secure log-ons to access the secure e-prescribing network. At the pharmacy, prescriptions are received only through trusted partners or agents. Electronic audit functions document, including time-date stamps and who touched the prescription, at each point in the process.

- The written prescription is "hard" evidence of the prescriber's order and the actual dispensing of the controlled substance.

E--prescribing does that as well. Electronic prescriptions will provide pharmacists with a higher level of confidence in the authenticity of prescriptions, which can only be received from trusted partners and agents. E-prescribing systems can help identify improper prescriptions and patterns of irregular use.

- "Hardcopy" prescriptions and so-called "wet" (ink) signatures provide a level of non-repudiation and physical evidence necessary for criminal legal proceedings

Yet e-prescribing system records can offer equally valid legal evidence of ownership and the e-prescribing infrastructure can provide a mechanism for third-party auditing and establish accountability for the prescriber.

What about drug diversion and illegal prescribing of controlled substances by "rogue" Internet pharmacies?

Identifying and prosecuting diversion of controlled substances currently requires the time-consuming and expensive process of sifting through thousands of paper prescriptions in disparate locations. The electronic audit trail of e-prescribing allows for faster identification and investigation of possible abuse.

Another avenue for abuse of controlled substances is patient "doctor shopping" and re-use of prescriptions. Since e-prescribing passes directly from the doctor to the pharmacy, there is no opportunity for abuse or diversion by the patient.

The e-prescribing infrastructure is a closed system. In order to receive e-prescriptions, pharmacies must be registered and certified to access the secure networks transmitting the prescriptions. Therefore, "rogue" Internet pharmacies would not be able to bypass these stringent safeguards.

What are the next steps?

The time has come to permit e-prescribing of controlled substances. The Drug Enforcement Administration and the Department of Justice need to promulgate regulations immediately for e-prescribing of controlled substances. These rules need to –

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- be technology neutral;
- build on today's safe and secure e-prescribing infrastructure;
- take into account the unique needs of prescribing in institutional settings, such as nursing homes, correctional facilities, and assisted living facilities; and
- allow for future changes and growth in technology, privacy and security safeguards, and industry expansion.

Attachment 3

e-Prescribing Controlled Substances Coalition

Controlled Substances and e-Prescribing: Saving Lives, Reducing Costs, and Helping Law Enforcement

Introduction

Federal laws and regulations prohibiting controlled drug substances from being electronically prescribed are an impediment to the widespread adoption of electronic prescribing. The purpose of this white paper is to describe the e-prescribing process and how e-prescribing can be used to safely and securely transmit prescriptions for controlled substances. It also describes how the current inability to e-prescribe controlled substances is hindering e-prescribing adoption, and how e-prescribing can help law enforcement with drug diversion control.

E-prescribing is the use of healthcare technology to improve prescription accuracy, increase patient safety and reduce costs, as well as enable secure, real-time, bi-directional, electronic connectivity between clinicians and pharmacies. This is achieved by providing prescribers with a secure means of electronically accessing health plan formulary, patient eligibility and medication history at the point of care and securely transmitting the prescription electronically into the pharmacy's computer system, which also is bi-directional, meaning that messages can flow back from the pharmacy to the prescriber.

E-prescribing also gives the provider access to real-time patient clinical decision support information at the point of care. This includes:

- Patient pharmacy benefit eligibility & coverage
- Formulary information
- Medication history information
- Drug-drug interactions and allergies

E-prescribing is *not* transmitting raw patient information over the open Internet. Prescriptions and other information are transmitted through secure, private networks. Prescribers and pharmacies must be credentialed and approved before they can participate in the e-prescribing process. They also must securely log on before they can

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e-prescribe or receive a prescription. Infrastructure technology partners, vendors and others are bound through strong contracts to ensure the authentication of users, the integrity of prescriptions, and the privacy and security of personal health information that passes through the secure networks.

The e-prescribing business model is very robust, with double digit growth in e-prescribing volume and in eligibility requests over the past five years. Industry analysts believe this will continue in the near future. The model also is self sustaining, with costs shared among the participants:

- Clinicians (usually physicians) pay for the e-prescribing or electronic health record systems.
- PBMs/health plans pay for the patient-level decision support information (eligibility, formulary, medication history) to be delivered to the prescribing clinician at the point of care.
- Pharmacies pay for their e-prescribing systems and also pay transaction fees when they receive electronic prescriptions and prescription renewal authorizations.

Underlying the business model is a secure and robust infrastructure, which is in operation today and transmits prescriptions to the patient's pharmacy of choice. Infrastructure providers include RxHub, SureScripts, Emdeon, Relay Health and eRx Network.

The model also results in enhanced patient convenience, preservation of patient choice, reduced costs for payers and patients, improved patient safety, increased efficiency for clinicians and pharmacies, improved medication compliance for patients, and better quality of patient care.

E-Prescribing Saves Lives, Improves Quality, and Reduces the Costs of Care

A paperless prescribing system is preferable to today's paper world because it adds new dimensions of safety and efficiency to current practice. Errors can occur at many points in the paper-based medication prescribing and delivery system; many of these potential points of error are due to failures in process and communication. These include:

- Miscommunication due to illegible handwriting
- Unclear abbreviations and dose designations
- Unclear telephone or verbal orders
- Ambiguous orders and fax-related problems
- Complex benefits plans
- Complex prescription regimens and dosages
- Wide range of drug choices for treating a medical problem
- High incidence of Adverse Drug Events (ADEs) and error rates

In 2006, the Institute of Medicine (IOM) recommended that all prescriptions be written and received electronically by the year 2010. Recognizing the problems of today's paper system detailed in the IOM report, and recognizing the benefits of e-prescribing and the

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opportunities to reduce the costs of care, many are calling for the increased use of e-prescribing in Medicare Part D. For example, a coalition of nearly two-dozen key stakeholders, including the Pharmaceutical Care Management Association, recently called on Capitol Hill leaders to require mandatory use of e-prescribing for prescriptions for Medicare beneficiaries. That need was echoed in similar requests from the Blue Cross/Blue Shield Association of America and the e-Health Initiative.

Many State governments and public/private partnerships have taken the initiative to launch or support programs that encourage the adoption of e-prescribing technology as an effort to reduce costs and improve the efficiency, safety, and quality of patient care in their respective states. State initiatives include e-Prescribe Florida, and efforts in Minnesota, Mississippi, New Hampshire, and Tennessee.

E-prescribing also provides better patient compliance with their therapeutic regimens. Medication noncompliance is a huge problem for the American health care system. Medication noncompliance is the failure to take drugs as prescribed, which can include not taking a medication on time, taking a different dose, or not taking the medication at all. In general, prescribing clinicians are unable to determine if their handwritten prescriptions are filled or not. Identification of unfilled, handwritten prescriptions is a very labor intensive process, requiring manual review by a number of pharmacists and others.

Noncompliance is dangerous and expensive for the prescribing clinician, patient, and health plan. Non-compliance with prescription medication causes an estimated 125,000 deaths annually and costs at least $75.6 billion each year.[1] Other impacts include such adverse outcomes as avoidable hospitalization, development of complications, disease progression, and premature disability.[2] The research and policy communities agree that these attributed adverse effects of medication noncompliance and related costs are substantially underreported. With e-prescribing, prescribers will know to which pharmacy a prescription has been sent and whether the patient has picked it up. This will offer opportunities for prescribing clinicians and pharmacists to better track and communicate about patient compliance.

In addition to the patient safety benefits, e-prescribing also offers cost savings resulting from the ability to identify the patient's formulary and benefit structure before the prescription is written. This helps the prescriber identify therapeutically appropriate alternatives that the patient's insurance will cover. The result is more affordable care for patients and payers through increased generic use and formulary compliance. For

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[1] Reminders Not Effective for Medication Compliance, Study Says. Research report from the Ohio State University. Retrieved 12/01/2006 at http://research news.osu.edu/archive/noncomply.htm.

[2] Dunbar-Jacob J, Mortimer-Stephens MK. (2001).Treatment adherence in chronic disease. J Clin Epidemiol 54(suppl 1):s57–s60. Ellis S, Shumaker S, Sieber W, Rand C. (2000). Adherence to pharmacological interventions: Current trends and future directions. Control Clin Trials: 21(Suppl):218–225. Jackevicius CA, Mamdani M, Tu JV. (2002). Adherence with statin therapy in elderly patients with and without acute coronary syndromes. JAMA 288:462–467.

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example, participants in the Southeast Michigan e-Prescribing Initiative (SEMI)[3] saw significant increases in generic use and formulary compliance through e-prescribing. With the use of e-prescribing for its workers and their families, General Motors has seen increases in its rates of generic drug prescribing and compliance with preferred drug lists, both of which save money. For each one-percent shift to generic drugs from a brand name, GM saves nearly $20 million. The Henry Ford Health System –another SEMI participant--conservatively estimates it is saving $4 million a year with e-prescribing, mostly from switching its patients from brand-name drugs to less costly generic alternatives.[4]

Finally, e-prescribing creates time and workflow efficiencies in pharmacies and clinicians' offices, such as through more efficient prescribing processes, more accurate medication orders and less manual intervention and rework for each prescription. E-prescribing also automates the prescription renewal authorization process, which is extremely time-consuming and labor intensive for both pharmacies and prescribers in today's paper world.

E-Prescribing is Safe and Secure

E-prescribing is far safer and more secure than today's paper world, in which prescription pads are stolen, home computers easily can print out counterfeit prescriptions, signatures can be easily forged, and drug quantities can be altered manually by patients before prescriptions are delivered to the pharmacy

The e-prescribing industry works diligently to ensure the privacy and safety of patient data, and the secure transmission of that data among the various points in the e-prescribing chain. The industry is constantly making changes to ensure that the infrastructure complies with the state of the art, as well as all federal and state standards, laws and regulations.

The industry also actively participates in professional organizations that develop and approve e-prescribing transaction, privacy and security standards, such as NCPDP, HL7 and ANSI. In addition, the e-prescribing industry participates in organizations relating to

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[3] SEMI is a broad coalition involving General Motors, Ford Motor Company, Chrysler LLC, the United Auto Workers (UAW), Blue Cross Blue Shield of Michigan, Health Alliance Plan, Henry Ford Medical Group, Medco Health Solutions, Inc.and CVS Caremark Corporation. SEMI has generated nearly 6.2 million prescriptions using e-prescribing technology since its launch in February 2005. Today there are nearly 2,500 physician participants writing more than 282,000 e-prescriptions each month. Recently released findings show that e-prescribing substantially improved patient safety by alerting physicians of risks related to drug interactions and other potential medication problems and resulted in a significant number of prescription changes that prevented possible adverse events. Based on the program's success thus far, the SEMI coalition partners will extend the e-prescribing initiative into 2008, continuing to enroll physicians through March. (Source: SEMI press release 10/29/07)

[4] Kosmetatos, Sophia. (2007, October 29). Online Rx program helping cut errors. *Detroit News*.

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the security and interoperability of health information technology. For example, RxHub and SureScripts, are among the e-prescribing infrastructure companies that are certified members of the Electronic Healthcare Network Accreditation Commission (EHNAC), which is a nationally recognized accreditation body with focus on HIPAA privacy/security and improvement of quality and efficiency of healthcare. RxHub and SureScripts networks also are certified for interoperability testing through the Certification Commission for Health Information Technology.

- ***Reliable Authentication of Prescribers.*** Electronic prescriptions will provide pharmacists with a higher level of confidence in the authenticity of prescriptions. Prescriptions will be received only through trusted partners or agents, who have been credentialed and approved to access the secure networks. Prescribers and pharmacies also must securely log on before they can e-prescribe or receive a prescription. Infrastructure technology partners, vendors and others are bound through strong contracts to ensure the authentication of users, the integrity of prescriptions, and the privacy and security of personal health information that passes through the secure networks.

- ***Access to Data.*** E-prescribing systems, network infrastructure and related business practices must comply with all applicable state and federal laws. These ensure authentication before users can access the system, making sure that users really are who they say they are, and providing another layer of protection for patient data. Security procedures are in place to restrict access only to users and other entities in the e-prescribing chain who are contractually obligated to take measures to ensure data privacy in accordance with HIPAA requirements, state laws, and agreed-on business rules. HIPAA mandates that there must be a Business Associate Agreement (BAA) formally binding all covered entities and those they allow to access protected health information on their behalf to the Privacy and Security provisions of HIPAA. This includes e-prescribing vendors, pharmacies, data networks and data providers. Access to patient data is "role based," meaning that only certain people can access the system on a predetermined "need to know" basis. For example, office managers who need certain demographic data in order to schedule appointments do not have access to write prescriptions. Finally, these processes create additional safeguards for privacy and security that far exceed the minimal and fragmented practices in today's paper world.

- ***Security.*** E-prescribing networks must comply with all the security provisions of HIPAA. This includes encryption for all exchanges that involve personally identifiable information from the point of prescribing to the point of dispensing. Server operating systems are "hardened," containing only essential system software. Firewalls enforce a strict access policy for contracted participants and log all traffic on the network. Network intrusion detection systems are in place, and systems are continually monitored and upgraded to prevent breaches. Internal assessments are done periodically using scanning tools to ensure network and system security and annual security risk assessments are conducted using

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specialists trained in this field. Data are encrypted before going off-site for backup/disaster recovery purposes.

E-Prescribing and Controlled Substances

Accelerating Adoption of e-Prescribing and EMRs. E-prescribing could be used for controlled substances, but is not allowed at the present time under federal law and regulations promulgated by the Drug Enforcement Administration (DEA) and the Department of Justice (DOJ). Although the proportion of prescriptions for controlled substances is modest--the DEA has estimated that such prescriptions account for up to a fifth of total prescription volume-- the ability to prescribe them electronically will accelerate e-prescribing adoption. That is because a large number of prescribing clinicians are waiting to purchase a system that will prescribe the complete range of drugs their patients need.

E-prescribing of controlled substances will also increase the development and adoption of electronic medical records (EMRs), as the medication history developed through the electronic prescribing process is a major building block for EMRs and for which a complete medication history (including all prescribed drugs) will be essential. Federal policymakers and a growing number of Congressional and state legislators are calling for e-prescribing for controlled substances to enable public and private payers, consumers and others to fully take advantage of the safety benefits, quality of care improvements and increased cost savings accruing from e-prescribing.

Similarly, the current inability to e-prescribe controlled substances is hindering e-prescribing adoption in nursing facilities and other institutional settings, including assisted living facilities, correctional facilities, hospices, and group homes. All patients in institutional settings would benefit from the ability to prescribe controlled substance medication orders electronically. In order for prescribing to work in institutional settings, however, some changes would be needed to DEA regulations. For example, the DEA's definition of "LTC Facility" must be expanded to specifically include assisted living facilities and other sites of care, such as hospices. This will be important because current DEA regulations only name "nursing homes, retirement care, mental care or other facilities or institutions which provide extended care to resident patients."

Enhancing patient safety and quality of care. E-prescribing could easily be used to prescribe controlled substances, as the infrastructure exists to handle such transactions and prescription claims currently capture controlled substances. This also could enhance patient safety and quality of care, because the controlled substance information could then be added to a patient's medication history. This will give prescribers a complete picture of all the drugs a patient is taking. The e-prescribing decision support will identify drug-drug interactions, allergies, and other problems from all the medications a patient is taking. Not having this information creates unnecessary holes in the prescribing and clinical decision support processes that could have adverse consequences for patients.

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E-prescribing and Drug Diversion and Diversion control

Stopping Abuse and Helping Law Enforcement. Federal and State officials are struggling to keep pace with identifying and prosecuting the diversion of controlled substances. This is further slowed and complicated in today's paper world by the time-consuming and expensive process required for law enforcement staff to painstakingly sift through thousands of paper prescriptions in disparate locations, many months after the fact.

E-prescribing offers a potential solution today to these challenges by helping identify drug abuse and diversion of controlled substances, as well as being a tool for assisting law enforcement create documentation for prosecution of drug diversion. When the paper prescription (printed or written) is removed from the patient's hands, a key capability to deter patient abuse is established. Through its ability to provide at the point of care a patient's medication history and prescriber relationships that the patient has established, e-prescribing achieves a critical care and safety component that additionally greatly reduces the opportunity for patient abuse. In addition, e-prescribing addresses loss of forensic evidence. With appropriate authentication and security/audit controls, proof of prescribing should be maintained. E-prescribing also offers real-time controlled substance reporting and monitoring capabilities that allow the DEA, as well as state and local law enforcement agencies, the ability to identify potential abuse immediately rather than days or weeks after dispensing.

Putting an end to "doctor shopping." E-prescribing also could help to quickly identify patients who doctor shop and garner multiple prescriptions for controlled substances. E-prescribing additionally creates an immediate electronic audit trail that is documented and time-stamped through each point in the process, from the prescribing clinicians' office to the pharmacy. These electronic audit trails show who touched the prescription and when. If the prescription is created and sent electronically, these built-in audit trails also could be used to identify drug shopping, even if the patient pays cash. These records, when subpoenaed, could assist law enforcement in prosecuting diversion control cases, much as is done in today's reactive process.

Guarding against rogue Internet pharmacies. Pharmacies and e-prescriber systems must be registered and certified to access the secure networks and e-prescribing infrastructure provided by RxHub, SureScripts and others. Further, contracts are in place among the participating parties to ensure that prescribers and pharmacies are credentialed and authorized to use the infrastructure. Rogue Internet pharmacies would never pass these stringent safeguards.

It should be noted that there is no silver bullet and that e-prescribing cannot address every instance of drug diversion. E-prescribing, however, will help eliminate illicit prescribers and facilitate the identification of illicit prescribers and prescription channels, which will help mitigate the problem over time.

Conclusion

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E-prescribing is safe and secure. It is an effective tool that is saving lives, improving the quality of healthcare and reducing the costs of care. The inability to e-prescribe controlled substances is preventing patients, prescribers and payers from taking advantage of these benefits. Moreover, the inability to e-prescribe controlled substances is depriving law enforcement of a tool that could help stop illicit prescribing and doctor shopping and assist with diversion control.

The time has come to permit e-prescribing of controlled substances. The DEA and DOJ need to promulgate regulations immediately for e-prescribing of controlled substances. These rules need to be technology neutral; build on today's safe and secure e-prescribing infrastructure; and allow for future changes and growth in technology, privacy and security safeguards, and industry expansion.

The rules also should take into account e-prescribing for controlled substances in institutional settings where an electronic prescription/order must be sent from the prescriber to the pharmacy and facility/institution. The definition of facility should be expanded not only to include nursing homes, but also assisted living facilities, correctional facilities, hospices, group homes, etc. The unique, three-way communication in these settings will need to be addressed in DEA regulations and applicable standards.

Forthcoming rules also need to preserve some of the features of today's regulations with respect to long-term care and institutional settings, such as allowing facility nurses to act as the agent of the prescriber. This should be the case for controlled substance electronic prescribing as well.

In conclusion, the country can no longer afford to have a two-tiered process for prescribing controlled substances. E-prescribing for controlled substances is needed now, and can be made possible through expedited rulemaking. It is time for the e-prescribing and law enforcement communities to work together to harness all of the attendant benefits that health information technology can provide to the nation's health care system and the consumers it serves.

The Honorable Sheldon Whitehouse
Hart Senate Office Building
Room 502
Washington, D.C. 20510

December 11, 2007

RE: ePrescribing of Medicines Containing Schedule II Controlled Substances

Dear Senator Whitehouse:

Diversion of prescription medicines containing controlled substances is a serious problem in the United States of America with individual and societal costs involving law enforcement, public safety, drug abuse and addiction, and their attendant medical and social ramifications. Diversion can occur by various means, but one factor common to several related methods is written prescriptions presented to pharmacists by persons without legitimate medical purpose for the medicines requested.

Persons desirous of obtaining controlled substances for unlawful purposes may:

- Alter the quantity or strength of a controlled medicine specified on a written prescription,
- Create counterfeit prescription blanks that are fraudulently filled out,
- Steal *bona fide* prescriptions from a practice and fraudulently fill them out,
- Replace the name of a non-controlled medicine with a controlled medicine via a process known as "rinsing", or
- Add a controlled substance to a prescription for a non-controlled medicine, where states allow more than one medicine to be dispensed on the same prescription blank.

Allowing ePrescribing, the secure electronic transmission of authorization to dispense medicines containing substances that are in Schedule II of the Controlled Substances Act of 1970, will create a communication channel between the prescribing practitioner and the dispensing pharmacist that will preclude the opportunity for any of the behaviors listed above that contribute to diversion. Expanding this to medicines in the other schedules of controlled substances, even though it is not necessary for those medicines, as prescriptions for those drugs can currently be communicated by facsimile, verbally or by the use of written prescription, would also reduce diversion of these medicines by the methods outlined above.

In addition to reducing diversion by the means outlined above, an electronic prescription system could reduce medication errors resulting from illegible handwriting. If properly configured on either the prescribing or the dispensing end of the transaction, drug-drug interactions could be avoided.

To be effective, this should be a voluntary option initially, and there should be no difference between a written prescription for CII medicines and one that is transmitted by a secure electronic means. For example, the recently issued rule to allow the option for a practitioner to issue multiple prescriptions for particular patients with instructions to the pharmacist to dispense no sooner than a specified date should be allowed by an electronic method.

Such a system should be driven solely by concerns about public safety and public health and should not in any way limit access to appropriate and effective pharmaceutical care for legitimate medical purposes. Nor should such a system interfere in any way with the legitimate practitioner-patient relationship. Any rule that enables ePrescribing should include language to protect these vital aspects of health care to which Americans are rightly accustomed.

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Vice President, Risk Management & Health Policy
Purdue Pharma L.P.

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VP, Medical Department/Senior Medical Officer
Endo Pharmaceuticals

Jeff M. Myers
VP Government Affairs and Public Policy
Cephalon, Inc.

Cc Senator Patrick Leahy (D-VT)
Senator Joseph Biden (D-DE)
Senator Arlen Specter (R-PA)

53359.035

Statement of

SureScripts, LLC

Before

The Senate Committee on the Judiciary

Electronic Prescribing of Controlled Substances: Addressing Health Care and Law Enforcement Priorities

December 4, 2007

Presented by:
Kevin D. Hutchinson, President & CEO

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Statement of
SureScripts, LLC
before
The Senate Committee on the Judiciary
December 4, 2007

Presented by:
Kevin D. Hutchinson, President & CEO

Electronic Prescribing of Controlled Substances:
Addressing Health Care and Law Enforcement Priorities

Chairman Leahy, Ranking Member Specter, and distinguished Committee members, thank you for the opportunity to testify today on behalf of SureScripts on the important topic of the electronic prescribing of controlled substances.

My name is Kevin Hutchinson, and I am the president and chief executive officer of SureScripts. In addition, I am a member of the Board of Directors of the eHealth Initiative, and a commissioner, appointed by Secretary Leavitt of Health and Human Services, to the American Health Information Community.

We at SureScripts have been interested in the implementation of electronic prescribing for controlled substances for several years, and we are pleased to share our experiences and views on this very important matter.

SureScripts was created by the National Community Pharmacists Association ("NCPA") and the National Association of Chain Drugs Stores ("NACDS") in 2001. Our mission is to improve the overall prescribing process and to ensure, among other things, neutrality, patient safety, privacy and security, and enforce a patient's ability to choose their pharmacy and a physician's ability to choose the appropriate therapy without encountering any commercial messages within the process of prescribing a medication. Under the leadership and with the backing of the pharmacy industry, SureScripts has created a neutral and secure network that is compatible with all major physician and pharmacy software systems.

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What is electronic prescribing: put simply, it is the private and secure electronic delivery of prescription and other healthcare information from a prescriber's computer to the computer of the pharmacy, and back again. Allow me to point out what the term e-prescribing does "NOT" include: it is not using a computer generated fax; it is not sending a prescription in an unsecure manner over the internet; and it does not entail unlicensed or rouge internet pharmacies. The pharmacies that are connected to the network are duly licensed and legitimate retail and mail order pharmacies.

The case for electronic prescribing is compelling. According to the Center for Information Technology Leadership (CITL), every year, more than 8 million Americans experience Adverse Drug Events (ADEs). CITL's research estimates that, by addressing ADEs caused by preventable medication errors, e-prescribing systems with a network connection to pharmacy and advanced decision support capabilities can help avoid more than 2 million ADEs annually -- 130,000 of which are life-threatening. Electronic prescribing will also save money. To take one example, the Henry Ford Health System in the state of Michigan states that it saved more than $1 million in 2005 and 2006 with the use of e-prescribing. By increasing use of generics, reducing administrative costs and decreasing the number of adverse drug events, e-prescribing is estimated to help Henry Ford increase its savings to $1.7 million for 2007, 2008 and 2009.

SureScripts was founded in late 2001. During its first two years, the Company focused on development of the technology necessary to transmit prescription information electronically. The Company's services were first put into production, sending and receiving electronic prescription transactions, in January, 2004. Today, more than 95 percent of the nation's pharmacies have computer systems that have been certified for a connection to the Pharmacy Health Information Exchange, and 70% of nation's pharmacies are live on the network today. In addition, physician software vendors including electronic medical record vendors and stand alone electronic prescribing applications, whose combined customer base represents well over 150,000 prescribing physicians, have contracted and certified their applications on the nation's Pharmacy Health Information Exchange.

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Electronic prescribing with respect to non-controlled substances is a reality today. In 2007, 35 million prescription transactions will have been routed electronically in the U.S., over 35,000 prescribers will have been utilizing e-prescribing in the U.S., and over 40,000 pharmacies will have been e-prescribing in the U.S. This represents 70 percent of pharmacies in the U.S. In fact, more prescribers electronically prescribed in the first 10 months of 2007 than in all of 2004, 2005, and 2006, combined, and there were more electronic prescriptions transmitted in the first eight months of 2007 than in all of 2004, 2005, and 2006, combined as well. For 2008, SureScripts estimates the number of prescription transactions routed electronically will grow to over 100 million. We estimate that, in 2008, the number of electronic prescribers will grow to approximately 85,000. And finally, for 2008, SureScripts estimates the number of e-prescribing pharmacies will grow to 45,000. Today, SureScripts is issuing the *National Progress Report on E-Prescribing*, an "at-a-glance summary" of key statistics detailing the status of e-prescribing adoption and utilization in the U.S.

The deployment and use of electronic medical records is a bi-partisan priority of Congress, as well as a priority of President Bush's Administration. The automation of the prescribing process is considered by many to be the first step in the deployment of robust electronic medical records. Many would argue that if we cannot get providers to take the first step of e-precribing, then how can we expect them to adopt a full fledged electronic medical record system. Federal policymakers and a growing number of Congressional and state legislators are calling for e-prescribing of controlled substances to enable public and private payers, consumers and others to take full advantage of the safety benefits, quality of care improvements and increased cost savings accruing from e-prescribing.

Adoption and utilization of e-prescribing is on the rise, but there are still barriers to adoption, and one of the significant barriers is the fact that prescribers cannot process controlled substances electronically. This prohibition directly affects more than the 11 to 13% of prescribed medications in the U.S. today that are controlled substances.

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Prescribers want and need to use just one tool and one process to prescribe their patient's medications. Using one process for one drug and another process for a second drug is inefficient, dangerous, and unnecessary. Consider a physician that is about to prescribe both controlled and non-controlled medications to his/her patient, but cannot use electronic prescribing for all of the prescriptions. As a result, part of the prescriptions are written electronically in which an automatic drug interaction check is performed and the remaining drugs, which are controlled substances, are written by hand and no drug interaction check is performed against those medications leaving the patient vulnerable to an adverse drug event. The more likely case is the prescriber chooses to just use the paper and pen to issue all of their patient's prescriptions and the advantages of automatic drug interaction checks and use of available clinical decision support tools is lost. Time and time again we hear from prescribers that they will not e-prescribe at all because they cannot process controlled substances electronically. Accordingly, the DEA prohibition affects not just the 11 to 13% of controlled substances, but a far greater number of precriptions. This is truly a barrier to adoption.

We agree that the criminal element is interested in leveraging today's paper based process using fraudulent means to obtain schedule II through V medications. And we absolutely agree that the DEA and other law enforcement officials need the necessary tools to find and prosecute those who abuse drugs and break the law. We believe, however, that the current system used for e-prescribing supports the highly secure transmission of prescriptions, regardless of schedule. We believe that today's system of e-prescribing would enhance, not deter, law enforcement. E-prescribing is far safer and more secure than today's paper world, in which prescription pads are stolen, home computers easily can print out counterfeit prescriptions, signatures can be scanned and forged easily, and drug quantities can be altered manually by patients before prescriptions are delivered to the pharmacy. In fact, Congress has already concluded that e-prescribing is a substitute for paper and pen with respect to the prevention of fraud. In Section 7002(b) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007, Congress mandated the use of tamper proof pads for all Medicaid prescriptions, but specifically allowed for e-prescribing as an

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alternative even to tamper proof paper. Among other things, the law aimed to prevent patients from illegally obtaining controlled drugs. Accordingly, Congress already has recognized that e-prescribing prevents fraud as much, if not more, than the vulnerable paper based system that exists today. When the paper prescription is removed from the hands of the patient, that in and of itself is a key deterrent to fraud and criminal activity.

The business and technical structure of e-prescribing provides a framework for the secure and auditable transmission of a prescription. All transmissions are processed using secure connections such as private leased lines or secure and encrypted Internet connections using either a virtual private network or secure socket layer encryption techniques equivalent to those used in on-line banking and e-commerce transactions today. Moreover, e-prescribing networks must comply with all of the security provisions of HIPAA, the federal privacy law, as well as applicable federal and state laws regarding privacy and security of systems that transmit personally indentifiable health information.

The current e-prescribing system also allows for the tracking of prescriptions on a real-time basis, which is not possible at least in a timely and scalable way with the paper processes in place today. E-prescribing could help law enforcement to quickly identify, in real time, patients who doctor shop and garner multiple prescriptions for controlled substances. E-prescribing additionally creates an immediate electronic audit trail that is documented and time-stamped through each point in the process, from the prescribing clinicians' office to the pharmacy. These electronic audit trails show who touched the prescription and when. If the prescription is created and sent electronically, these built-in audit trails also could be used to identify drug shopping, even if the patient pays cash. These electronic records, available from the proactive process that is now live in all 50 states and the District of Columbia, when subpoenaed, could assist law enforcement in prosecuting diversion cases in a much more timely and efficient manner than today's reactive process.

Accordingly, we call upon Congress to encourage the adoption of regulations that would allow for the electronic prescribing of controlled substances. Such regulations should set

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forth policy that achieves the goals and mandate of law enforcement authorities, and not mandate particular technologies. E-prescribing as currently conducted not only will enhance law enforcement, but will advance the legislative agenda of promoting electronic health records, which will save the federal government millions of dollars and will save lives. We at SureScripts thank the Committee for the opportunity to share our experiences with respect to electronic healthcare, and it would be my pleasure to answer any questions that you might have.

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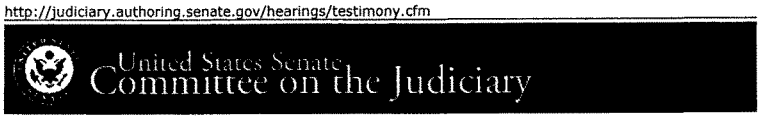

< Return To Hearing

Testimony of

The Honorable Tim Johnson

December 4, 2007

STATEMENT REGARDING ELECTRONIC PRESCRIBING OF CONTROLLED SUBSTANCES

Mr. JOHNSON. I wish to thank Senator Whitehouse for calling this hearing on such a critical topic to patient safety and law enforcement as electronic prescribing of controlled substances. Advances in technology present us with a unique opportunity to improve patient safety, reduce costs and increase physician efficiency through use of electronic prescribing, all while improving law enforcement's ability to monitor use of these pharmaceuticals. I am hopeful that Senator Whitehouse's efforts will be successful in moving the practice of prescribing controlled substances out of a paper-based system rife with insecurities and inaccuracies and into a secure, accurate and safe electronic environment.

I am a long-time supporter of telehealth initiatives, and I am proud that my home state of South Dakota is a leader in developing and implementing telehealth. Health systems throughout South Dakota utilize telehealth technology for many different initiatives, including telemental health services and electronic Intensive Care Unit (eICU) monitoring. Health care providers in South Dakota have found that patients monitored in an eICU bed experience reduced mortality risk and reduced hospital length of stay. In addition to these benefits, rural hospital physicians, often the only physicians in their communities, are relieved of overnight calls and have access to peer consultation, all while keeping health care dollars in the local community, because patients are not transferred to an ICU in a larger community. Telehealth technology is critical to ensuring that rural communities receive quality health care and increased access to specialists. Electronic prescribing is a natural extension of these telehealth initiatives, and health care providers in South Dakota are eager to explore the use this technology. Electronic prescribing, also called e-prescribing, is a prescriber's ability to electronically send an accurate, error-free and understandable prescription directly to a pharmacy from the point-of-care. E-prescribing has the potential to increase patient safety, increase physician efficiency, and reduce cost. The Institute of Medicine acknowledged the promise of e-prescribing in its July 2006 report entitled Preventing Medication Errors, and recommended that by 2010 all prescribers and pharmacies be using e-prescriptions.

Under the Medicare Modernization Act of 2203 (MMA), e-prescribing is optional for physicians and pharmacies, but drug plans participating in the new prescription benefit are required to support electronic prescribing by 2009. The Centers for Medicare and Medicaid Services (CMS) is engaged in the rulemaking process regarding standards for e-prescribing of prescription drugs (except controlled substances), which are expected to be finalized by April 2008. Because state boards of pharmacy control prescription-writing requirements, states will also need to create standards, and many are poised to do so. In South Dakota, two task forces are at work developing standards and regulations for use of e-prescribing.

Unfortunately, the part of the federal government with jurisdiction over approximately 15 percent of all prescribed drugs does not appear to be joining in the exploration of this technology. Controlled substances in Schedules II – V constitute approximately 15 percent of all prescriptions, and the Drug Enforcement Administration (DEA) within the Department of Justice regulates prescription-writing requirements for controlled substances. Three years after first proposing regulations for e-prescribing, and more than one year after a public forum on the issue, it appears to this outside observer that DEA is uninterested in deploying e-prescribing for controlled substances. I am disappointed in the DEA's lack of progress on this issue, particularly in light of the Institute of Medicine's conclusions that e-prescribing can avoid many of the mistakes inherent in handwritten prescriptions, allow for automatic checks of drug allergies and drug-drug interactions, and avoid errors that occur when prescriptions are handed between several different health care providers and the patient. In addition, DEA's actions are at odds with the Medicare Modernization Act of

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2003, which mandates that drug plans participating in Part D support electronic prescribing by 2009. Without guidance and standards from DEA regarding e-prescribing of controlled substances, drug plans will be unable to meet this mandate. I urge the DEA to rejoin the dialogue regarding e-prescribing.
Again, I thank Senator Whitehouse for his leadership on this very important issue, and I look forward to learning more about the government's progress in establishing standards and regulations for electronic prescribing of controlled substances.

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Congressional Testimony
December 4, 2007

Written Statement of
David C Miller
Chief Security Officer
Compuware Covisint

Introduction

Chairman Leahy, Ranking Member Specter, and distinguished Members of the Judiciary Committee, I want to thank you for the opportunity to discuss electronic prescribing of controlled substances. Given the fact that all types of communication in our country are shifting away from face-to-face in favor of electronic media, it is vital that we consider the advantages of electronic commerce in all areas of the economy. This holds particularly true in the healthcare industry where controlling costs, protecting privacy and sharing information effectively will have an impact on every United States citizen.

In the years that I have been working as a security expert at EDS, IBM, General Motors, and now with Compuware Covisint, I have become very familiar with the challenges related to securing transactions on the public internet, considered by some to be an inherently insecure network. Covisint was created to leverage the internet in a secure way, such that automotive companies could take advantage of the technology without being exposed to this risk. As a result, Covisint's solution evolved as a unique information sharing hub providing a service for communities of interest to collaborate and securely exchange information.

The concerns of the automotive industry parallel those of the DEA in e-prescribing controlled substances, albeit for different reasons. In building a secure information sharing hub, the Covisint solution had to manage these electronic communications; it was our responsibility to create a system that could support the secure communication issues of a diverse community while keeping cost and implementation time to a minimum.

As Covisint expanded its business landscape and grew into other industries (healthcare, law

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enforcement, financial services), we saw the same sort of challenges. Healthcare systems need to interact with each other, sending highly personal data back and forth, while maintaining compliance to HIPAA regulations. In law enforcement, Covisint helped create an information-sharing pilot for the Department of Justice to use in sharing sensitive terrorist-related information between law enforcement agencies. In each case, the challenge was to balance security with implementation cost and complexity. In a nutshell, a security solution that cannot be implemented or is only partially implemented may be worse than no security at all. What we have done for these institutions is to find that balance.

Electronic Communications Offer Security Advantages

Although some believe that paper-based transactions such as medical prescriptions are inherently secure, I believe that this is often not the case. Paper transactions are hard to track and manage. Paper transactions involve manual processes that are particularly vulnerable to human error. Paper transactions are difficult to store and retrieve without redundant processes to enter the transaction into an electronic format. Paper transactions are subject to a declining adherence and a declining attention to process as the people involved are asked to simultaneously support both the paper-based process and an electronic-based process. Although paper transactions can include a physical signature, this method of authenticating is based solely on the assumption that the recipient can successfully distinguish one signature from another.

In days past, we always went to the same doctor and always visited the same pharmacy. Doctors had relationships with pharmacists such that a voice and signature were readily recognized. Even doctor's prescribing habits were recognizable by pharmacists Pharmacists often picked up the phone to verify or inquire about the validity of a prescription. The days of

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tight relationships between doctors and pharmacists are quickly disappearing And the weakening of these relationships weakens the ability of pharmacists to validate signatures, recognize prescription patterns and otherwise ensure security associated with the paper process.

So what is the solution? Electronic transactions, whether on the internet or over a private network, offer us the best alternative today. With a set of electronic transactions, the prescribing activity of physicians can be tracked and monitored. Electronic transactions minimize human error and detect irregularities in activity. Electronic transactions are easy to store and allow extensive search capabilities. Processes in the electronic system can be highly controlled via predefined workflow. Electronic systems offer a variety of methods for authenticating the user and ensuring the user's authority to perform the transaction.

In terms of checks and balances, electronic transactions:

- can be supplemented with physical signatures, which can be faxed and appended to the transaction.
- can incorporate alerts and triggers in the workflow, for example alerting doctors of certain physician activities, such as prescribing a controlled substance. This is known as a closed loop transaction.
- can monitor pharmacies and warehouses to ensure their accuracy and honesty in filling and shipping prescriptions.

As demonstrated by these examples, it is important to remember that information security looks at both "bad guys" who are intruding on the system and "good guys" who have legitimate access but may abuse their access.

In general the advantages to e-prescribing are:

1) An audit trail

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With an electronic log of what is sent, when it is sent and who received it, you can provide true audit capability. This is important when you need to understand the patters of prescribing for physicians.

2) Real-time tracking

Electronic methodologies happen in real time. With paper-based systems it can take weeks for a trend or abuse to surface. In the electronic world, these activities are visible as they happen.

3) Transparency

In the electronic world, there is always an audit trail; a physician or pharmacist cannot hide their activities. This generic visibility creates transparency. Transparency is also a deterrent, as users are aware that they are constantly being monitored. The paper world offers opportunities for people to mask their activities.

4) Event alerts

As a result of the electronic nature of e-prescribing, monitoring for abusive behavior takes place real-time and provides alerts that can be acted on prior to dispensing the medication. With paper transactions, people need to be involved, and they become the bottleneck.

5) Trend and historical pattern analysis

Often the only way to see abuse is to discern patterns in historical data. This historical data could be millions of records over many months. In the paper world, managing this amount of data is difficult at best, impossible at worst. With electronic transactions you can do trend analysis in seconds instead of months.

Complexity of Securing Electronic Transactions

When considering the approach to secure these electronic transactions, the temptation is to

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implement the most sophisticated and secure technologies that are available to the industry. This can often be the death of an implementation. I have seen many cases of the security of the implementation being so complex that the users of the system have either found ways around the system, thus defeating the security implementation, or have made up excuses as to why "it won't work," and thus abandoning the system altogether.

In information security today, Public Key Infrastructure, or PKI, is that "sophisticated and secure technology." Although PKI- based authentication methods provide some superior functionality, the current state of the technology brings with it major implementation and usage challenges:

- The heart of the system relies on a very long numeric key. This key would be impossible for a user to memorize, so it is stored on a device called a container. This container can be a PC, or a card that understands PKI (e.g. a smart card). The key requirement is that the container if physically available to the prescribing physician. Thus, if the physician forgot his card or his PC is broken, no authentication can occur and no prescribing can occur. The physician is unable to perform a key task until the container is recovered. In addition, many PCs cannot handle the PKI container requirements and would need to be upgraded.
- Because the container or device holds the key, it too must be secured. In most cases, this requires some sort of pass phrase or password to use the key which unlocks the container. So in the end, a password is the true security method. Anyone who shares that password and allows others access to the container can circumvent the security
- Access to the container is paramount. If you are out of the office without your PC, then you would not be able to access the system. At face value this may seem like a good thing, but experience tells us that in today's world you cannot guarantee where a person is located when working. Many times physicians need to access their e-prescribing system while on call after hours, but without their work computer present at home, or wherever they may be, they cannot utilize the system. Or imagine if after Hurricane

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Katrina no physicians in New Orleans could provide healthcare because their computers were all underwater

Proven Alternatives

So if solutions such as PKI won't work, what alternatives do we have? I believe that by combining technology, process and oversight a solution can be provided that allows for appropriate levels of security for controlled substances while providing all of the advantages of e-prescription. This technique will allow for the authentication, integrity and non-repudiation, which we all want.

The components of this solution include:

- **A robust authentication capability**

  Authentication is very important to the implementation of a secure, transaction-based system. We all know the problems with passwords, such as:

  a. Users write down good passwords (difficult to guess)
  b. Users can memorize bad passwords (easily guessed)
  c Passwords are prone to hacker attacks

  In my experience there are additional technologies that can mitigate this. Multi-factor technologies allow an added degree of protection while still allowing for reasonable implementations.

  For example ***one time passwords*** are a method whereby the user is required to enter the code that is presented on a device that he carries all the time – such as a cell phone or keychain fob. Additionally, the user must enter a password that only he knows The advantage of these "token" based technologies is in order for another user to access as the original user they need to both have the device and know the password. The

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advantage over PKI is that the device in this case requires no computer interface such as the PKI container and thus can be used on any PC.

Another type of authentication is ***knowledge based***. In this model the user is asked a set of random questions that only he would know. This along with the password provides a two-factor system. This is exactly what is being used in many web banking systems in direct response to guidance from the FDIC.

- **A group of trusted identity providers**

  Another mitigating control is to identify a group of trusted identity providers or credential providers. The identity providers would need to be vetted as capable of providing highly secure authentication technology. The benefit of these organizations is that they allow users to leverage existing identities and thus reduces the number of passwords for a given user. Audit and logging capabilities would still be managed at the user level. Examples of possible identity providers would be large health systems, universities or major payer organizations or any trusted, technology-capable organization in the supply chain. This exact method is being utilized as part of both the e-authentication initiative and the Federal Law Enforcement Information Sharing Program (LEISP).

- **Third party "trusted broker"**

  Organizations often have a need to share transactions with each other where the organizations may not have complete trust with each other, or there is concern that organizations could collude to circumvent the process. In these cases, a third party trusted broker that has visibility to all of the transactions can facilitate an implied trust relationship while monitoring the community for non-compliance or collusion.

- **A consistent policy**

  Regardless of the technical approach, a consistent policy needs to oversee each of

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these possible implementations. This policy then can be implemented and enforced by the third-party trusted broker.

- **An oversight organization**

  As with any community it is imperative that an oversight organization be in place (e.g. DEA). This organization can draft and own the policy, manage and monitor the hub, and determine which technology is best suited for each implementation. It can also be the coordination point for the migration activities that will have to occur

Conclusion

Ultimately, the success of any system is all about adoption. Getting the constituents to adopt a new methodology will require selection of a cost-effective, simple and secure solution. I believe that there are simple-to-use authentication technologies, which--when partnered with policy and oversight--can achieve adoption within the whole healthcare community. This approach can also overcome the security concerns associated with enabling the e-prescribing of controlled substances. I have seen this approach work successfully in many industries over the past seven years and believe it has real merit and deserves further consideration.

Chairman Leahy, and members of the Committee, I thank you
for the opportunity to discuss this vital issue and welcome any questions you may have.

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Statement of:

The National Association of Chain Drug Stores

Submitted To:

The United States Senate
Committee on the Judiciary

For the Hearing:

"Electronic Prescribing of Controlled Substances: Addressing Health Care and Law Enforcement Priorities"

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December 4, 2007

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Thank you for the opportunity to present testimony on behalf of NACDS on the important topic of the adoption of electronic prescribing (e-prescribing) for controlled substances in the United States.

The National Association of Chain Drug Stores (NACDS) represents the nation's leading retail chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers. Chain pharmacies operate more than 38,000 pharmacies, employ 114,000 pharmacists, fill more than 2.4 billion prescriptions yearly, and have annual sales of nearly $700 billion. Other members include almost 1,000 suppliers of products and services to the chain pharmacy industry.

NACDS supports the testimony on this topic already submitted to this Committee by SureScripts, in addition to the concerns and positions we articulate in this statement. NACDS and the National Community Pharmacists Association ("NCPA") created SureScripts in 2001 as the foundation for an electronic prescribing network. Their mission was to improve the overall prescribing process and to ensure, among other things, neutrality, patient safety, privacy and security, and freedom of choice for a patient's choice of pharmacy and a physician's choice of therapy. Under the leadership, and with the backing, of the pharmacy industry, SureScripts has created an open, neutral, and secure information system, known as the Pharmacy Health Information Exchange, that is compatible with all major physician and pharmacy software systems.

NACDS and the chain pharmacy industry strongly support the widespread adoption of e-prescribing technology and practices, as evidenced by our creation of SureScripts. However, federal laws and regulations prohibiting controlled substances from being electronically prescribed and transmitted are an impediment to the widespread adoption of e-prescribing.

Benefits of E-prescribing are Well-Established

E-prescribing improves prescription accuracy, increases patient safety and reduces costs, as well as enables secure, real-time, bi-directional, electronic connectivity between clinicians and pharmacies. This is achieved by providing prescribers with a secure means of electronically accessing health plan formulary, patient eligibility and medication history and securely transmitting prescriptions and prescription information electronically to and from the pharmacy's dispensing system.

A paperless prescribing system provides enhanced safety to current medical and pharmacy practices. Despite tremendous care and safeguarding, errors may occur at many points in the medication prescribing system; many of these potential points of error are due to failures in process and communication. Electronically created and transmitted prescriptions streamline the prescribing process and eliminate many of the potential points of error. Some of the most common sources of errors occur when a prescription is ordered/written, and when a prescription is transcribed from a piece of paper into the pharmacy dispensing system. Electronically created and transmitted prescriptions can reduce or eliminate errors caused by these sources, especially when prescriptions are transmitted directly into a pharmacy's dispensing system.

Besides efficiency and patient safety, other benefits to e-prescribing include the following:

- Better patient compliance. Prescribers can know to which pharmacy a prescription has been sent and whether the patient has picked it up.
- More clear and readable prescription documentation. There is a complete and legible prescribing record at both the prescriber's office and at the pharmacy. Prescriptions cannot be misfiled or lost.
- Reliable authentication of prescribers. Electronic prescriptions provide pharmacists with a higher level of confidence in the authenticity of prescriptions. Prescriptions are received only through trusted partners or agents.

Congress has already recognized the benefits of e-prescribing. The Medicare Modernization Act (MMA) of 2003 requires that Medicare Part D plans support the ability of prescribers to send, and pharmacists to receive, electronic prescriptions for Medicare beneficiaries. Since NACDS recognizes the benefits of e-prescribing, we strongly supported including the e-prescribing provisions in the MMA.

E-prescribing does not enable Rogue Internet Sites

E-prescribing is *not* providing consumers with prescription drugs via the Internet. Rogue Internet sites operate outside of the realm of the legitimate practices of medicine and pharmacy, and do not have access to legitimate e-prescribing networks. Electronic prescriptions and related information are transmitted through secure, private networks. Prescribers and pharmacies must be credentialed and approved before they can participate in the e-prescribing process. They also must securely log on before they can e-prescribe or receive a prescription. Infrastructure technology partners, vendors and others are bound through strong contracts to ensure the authentication of users, the integrity of prescriptions, and the privacy and security of personal health information that passes through the secure networks. These security and privacy measures provide pharmacies and pharmacists with greater assurance about the legitimacy of the prescriptions they receive than with traditional paper and oral prescriptions.

E-prescribing Systems are Stronger than Current Prescribing Processes

The criminal element capitalizes on the weaknesses in the current paper and oral-based prescribing processes to divert and abuse controlled substances. We agree that the DEA and other law enforcement officials need the necessary tools to find and prosecute those who abuse drugs and break the law. Accordingly, we believe that current systems used for e-prescribing provide much better protection from the criminal element, and provide DEA and law enforcement with better tools to prosecute those who abuse and divert controlled substances. E-prescribing is far more secure than today's paper/oral prescribing processes, in which prescription pads are stolen, computers can easily can

print out counterfeit prescriptions, signatures can be scanned and forged easily, drug quantities can be altered manually by patients before prescriptions are delivered to the pharmacy, and unauthorized personnel can telephone prescriptions into pharmacies.

In fact, Congress has already concluded that e-prescribing is a substitute for paper and pen with respect to the prevention of fraud. In the Iraq Funding Bill of 2007, Congress mandated the use of tamper resistant prescription pads for all Medicaid prescriptions, but specifically allowed for e-prescribing as an alternative to tamper resistant paper. The law aimed to, among other goals, prevent patients from illegally obtaining controlled drugs. Accordingly, Congress already has recognized that e-prescribing is at least as secure and prevents fraud as much, if not more, than the paper based system.

E-Prescribing Systems are More Secure because They Have to Be

Pharmacies need assurances that all prescriptions received by way of any mechanism are confidential, authentic and have not been altered. Ideally, prescription delivery processes, whether they be for written, oral, or electronic prescriptions, can provide these assurances. For written and oral prescriptions, greater security requirements for controlled substance prescriptions are commensurate with the need for greater security, due to the greater risk of diversion of these products. However, for electronic prescriptions, the need for privacy, security and safety are equally important for both controlled and non-controlled substances. For example, all e-prescribing systems must comply with HIPAA and state-specific privacy and security requirements because they handle sensitive, protected health information. These privacy and security requirements ensure that only authorized individuals may access the protected health information that comprises prescriptions. The provisions that protect patient privacy and security will also protect against anyone attempting to access electronic prescribing systems for diversion purposes. E-prescribing systems could not reliably function without such protections from intrusion.

Pharmacies also must be assured that prescriptions received cannot be repudiated by the prescriber. That is, pharmacies must be assured that a prescriber cannot deny having written a prescription. Again, systems already in place, such as user registration and verification processes, user sign-on authentication requirements, and network auditing and monitoring procedures, ensure that a prescriber cannot repudiate an electronically transmitted prescription.

The e-prescribing industry works diligently to ensure the privacy and safety of patient data, and the secure transmission of that data among the various points in the e-prescribing chain.

E-prescribing Better Meets the Needs of Law Enforcement Officials

E-prescribing systems allow for the tracking and auditing of prescriptions on a real-time basis, which is not possible in a timely and scalable way with the paper processes in place today. E-prescribing could help to quickly identify patients who doctor shop and garner multiple prescriptions for controlled substances. E-prescribing additionally creates an immediate electronic audit trail that is documented and time-stamped through each point in the process, from the prescribing clinicians' office to the pharmacy. These electronic audit trails show who touched the prescription and when. If the prescription is created and sent electronically, these built-in audit trails also could be used to identify doctor shopping, even if the patient pays out-of-pocket. These records, when subpoenaed, could assist law enforcement in prosecuting diversion control cases, much as is done in today's paper world.

A Plea for Action

E-prescribing should be allowed for controlled substances, but it is not allowed at the present time under federal law and regulations promulgated by DEA. The percentage of controlled substances is estimated to be 11-13%. However, the inability to e-prescribe for controlled substances has been a hindrance to widespread prescriber adoption of e-

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prescribing. Many physicians and other clinicians are waiting to purchase a system that will allow them to prescribe the complete range of drugs their patients need. Clinicians are reluctant to invest in systems that will not allow them to prescribe all prescription drugs, and they resist having to use two systems for prescribing, as paper/oral is the only current option for controlled substances.

In conclusion, e-prescribing is safe and secure. It is an effective tool that is saving lives, improving the quality of healthcare and reducing the costs of care. The inability to e-prescribe controlled substances is preventing patients, prescribers and payers from taking advantage of these benefits. Moreover, the inability to e-prescribe controlled substances is depriving law enforcement of a tool that could help stop illicit prescribing and doctor shopping and assist with diversion control.

The time has come to permit e-prescribing of controlled substances. DEA and DOJ need to promulgate regulations immediately for e-prescribing of controlled substances. NACDS would like to thank the Committee for the opportunity to provide our perspectives on these matters.

With us, it's personal.

Statement of the
Rite Aid Corporation
for the hearing

"Electronic Prescribing of Controlled Substances:
Addressing Health Care and Law Enforcement Priorities"

United States Senate
Committee on the Judiciary

December 4, 2007

Rite Aid Corporation
30 Hunter Lane
Camp Hill, PA 17011
www.riteaid.com

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"Electronic Prescribing of Controlled Substances:
Addressing Health Care and Law Enforcement Priorities"

Chairman Leahy, Ranking Member Specter, Senator Whitehouse, and Members of the Senate Judiciary Committee. I am Mike Podgurski, Vice President, Pharmacy Services for the Rite Aid Corporation. I am a pharmacy graduate of the West Virginia University School of Pharmacy, and have been involved with many aspects of the practice of pharmacy for 35 years.

We thank you for this opportunity to provide testimony today for this important hearing regarding the electronic prescribing of controlled substances. Rite Aid, which is based in Camp Hill, Pennsylvania, is one of the nation's largest retail pharmacy chains. We operate approximately 5,100 pharmacies in 31 states and the District of Columbia.

Rite Aid Supports E-Prescribing for Controlled Substances

Rite Aid has been involved for many years in the development of the current electronic prescribing, or e-prescribing, infrastructure. For example, I was involved in the development of Rite Aid's own e-prescribing system in 1998. Our company has also been very actively involved in the development of the Pharmacy Health Information Exchange operated by SureScripts. This system currently serves as a secure platform for the transmission of all the e-prescriptions which Rite Aid receives today.

Rite Aid strongly supports the ability of prescribers to send and retail pharmacies to receive e-prescriptions for controlled substances. These include controlled substances in Schedules 2 through 5. We especially appreciate your support for this initiative, Senator Whitehouse, as you recently expressed in a colloquy with other Senators.

Rite Aid is also a member of the "E-Prescribing Controlled Substances Coalition", which includes stakeholders such as pharmacies, health insurers and PBMs, business related groups, and technology companies. This Coalition is encouraging the Congress and the Administration to develop a workable approach to allow electronic prescriptions for controlled substances.

E-Prescribing Can Help Reduce Paper Prescriptions

The health care system needs to increase the number of prescriptions that are transmitted electronically. About 3.2 billion prescriptions are filled in the United States each year. The majority of these prescriptions are still written by prescribers on little 3" by 5" pieces of paper, handed to the patient, and brought by the patient to the pharmacist for filling. In this day and age, the health care system can and must do better in using technology in transmitting all prescriptions to pharmacies, including controlled substances.

Each of our 5,100 pharmacies across the United States is currently able to receive – and does regularly receive - e-prescriptions. These include new prescription orders as well as approvals to refill existing prescriptions. The electronic transmissions of these new prescriptions and refill authorizations to our pharmacies have greatly enhanced the efficiency of our pharmacists in providing pharmacy services. This allows pharmacists additional time to interact with patients, and lessens the time the pharmacist spends on the phone trying to obtain refill authorizations, or clarify prescription orders with the prescribers' offices.

The frequency with which prescribers are sending prescriptions electronically is increasing. But, we need to encourage more prescribers to transmit new prescriptions electronically, and we need to permit and encourage those who do e-prescribe today to send *all* prescriptions electronically.

Allowing controlled substance prescriptions to also be sent electronically is an important step in accelerating the rate of growth in e-prescribing in general. Currently, about 13 percent of all prescriptions written are for controlled substances. We believe that prescribers would be more willing to make the necessary technology infrastructure changes in their practices if all prescriptions – including controlled substance prescriptions – were able to be sent to pharmacists electronically.

Benefits of E-Prescribing for Controlled Substances

There are multiple health care and efficiency benefits to e-prescribing for all prescriptions, including those prescriptions for controlled substances.

- First, e-prescriptions are easier for the pharmacist to read, which may reduce the chances that errors might be made in the filling of these prescriptions. It also reduces the likelihood that a pharmacist may make a transcription error when taking a prescriber's oral prescription order over the telephone.
- Second, before the prescriber sends an e-prescription to the pharmacy of the patient's choosing, the prescriber is able to perform an initial "drug interaction" or "adverse reaction" review to make sure that the new drug being prescribed does not conflict with a prescription drug that the patient is already taking.
- Third, e-prescribing provides significant convenience for patients. Using this system, prescribers can transmit prescriptions so that they are ready for the patient to pick up when the patient arrives at the pharmacy. However, because controlled substance prescriptions cannot be electronically transmitted, the patient convenience benefits of e-prescribing are significantly reduced. Non-controlled substance prescriptions can be sent, but controlled substance prescriptions cannot.

Why is this important? Let's use the example of an elderly dental patient that is prescribed both an antibiotic medication as well as a controlled substance painkiller.

This elderly patient can have her prescriber electronically transmit the prescription for the antibiotic to her pharmacy. The pharmacy would receive the e-prescription for the antibiotic and the pharmacist would fill the prescription so that it is complete and waiting for the patient when she is able to visit the pharmacy. This same patient, however, would still have to physically drop off the controlled substance prescription at her pharmacy and wait before it could be filled.

This is the same situation that a mother faces when needing to get a codeine-containing cough syrup prescription filled for a sick child. While a prescriber could phone in certain controlled substance prescriptions to the pharmacy, it is more secure if the physician transmits these prescriptions through the e-prescribing system.

Congress Recognizes Benefits of E-Prescribing

Congress has already recognized the multiple health care and efficiency benefits of e-prescribing. The Medicare Modernization Act (MMA) of 2003 requires that Medicare Part D plans support the ability of prescribers to send and pharmacists to receive e-prescriptions for Medicare beneficiaries. CMS has already developed certain foundation standards for e-prescribing and other proposed standards have been issued.

Congress also exempted e-prescriptions from the new requirements which go into effect on April 1st that Medicaid prescriptions be written on tamper proof paper. This means that Congress has already expressed its faith in the security of prescriptions being sent over the existing e-prescribing infrastructure.

E-Prescribing Can Reduce Diversion and Abuse

We understand and recognize the concerns of law enforcement agencies – including the Drug Enforcement Administration (DEA) - about the need to assure that e-prescribing does not result in additional diversion of controlled substances.

Rite Aid takes seriously our responsibilities to appropriately dispense and account for the controlled substances we purchase and provide to our patients, pursuant to legitimate prescriptions. However, we believe that e-prescribing of controlled substances will reduce diversion and abuse of controlled substances because of the significant security features incorporated into the e-prescribing system.

An increase in the electronic transmission of prescriptions may also help reduce the need for paper prescription pads. These paper prescription pads are more subject to theft and forgery. In addition, pharmacists make every effort to verify the authenticity of the person communicating oral prescriptions for controlled substances. However, the secure electronic transmission of controlled substance prescriptions may reduce the incidence of phony controlled substance prescriptions being called into a pharmacy.

Allowing e-prescribing of controlled substances should not be confused with policymakers' attempts to shut down the many rogue internet pharmacy sites that sell controlled substances to individuals without legitimate prescriptions. These sites should be shut down and eliminated. However, e-prescriptions are not sent over unsecured internet lines. E-prescriptions are only legitimate prescriptions, issued by licensed providers, and sent only to licensed and authorized pharmacies, all pursuant to standards established by the Department of Health and Human Services pursuant to the MMA.

We appreciate the efforts of Senators Feinstein and Sessions, and others on this Committee, in trying to eliminate these rogue internet sites through the bill that has already been reported out of this Committee, the "*Ryan Haight Online Pharmacy Consumer Protection Act of 2007*". However, we view these as two separate issues. Concerns regarding availability of controlled substances over the internet should not be used to impede or slow down adoption of e-prescribing of controlled substances.

Conclusion

In conclusion, we look forward to working with the Congress and the DEA to ensure that workable regulations are developed that would allow for the e-prescribing of controlled substances. We believe that e-prescribing of controlled substances would enhance medical benefits to patients, increase efficiencies in the prescribing and dispensing of controlled substances, and reduce – not increase – the potential for diversion and abuse of these substances. I look forward to answering any questions you may have. Thank you.

Statement of

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration

Regarding

"Electronic Prescribing of Controlled Substances: Addressing Health Care and Law Enforcement Priorities"

Before the

Senate Judiciary Committee

December 4, 2007

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Introduction

Chairman Leahy, Ranking Member Specter, and distinguished members of the Senate Judiciary Committee, thank you for the opportunity to appear today to discuss the Drug Enforcement Administration's (DEA's) ongoing efforts in establishing an appropriate system that allows electronic prescribing to be used for controlled substances while ensuring adequate safeguards are in place to prevent the diversion of controlled substances.

DEA supports the use of technology to reduce medical errors, streamline the medical process and increase efficiency. However, DEA must balance this objective with its legal responsibility to ensure there is a closed system of distribution for controlled substances in order to minimize the risk that these substances will be diverted and used illegally. Therefore, it is extremely important to understand the need for specific requirements when establishing standards for a system that allows electronic prescribing for controlled substances. It is critical that the technology and standards to be employed include adequate security that incorporates authentication, nonrepudiation, and integrity in the recordkeeping process. These three security-related elements are necessary to ensure that DEA can fulfill its obligations under the Controlled Substances Act (CSA).

DEA's Legal Authority and Responsibilities

By delegation from the Attorney General, DEA is responsible for the implementation and enforcement of the CSA. The CSA and its implementing regulations are designed to ensure an adequate supply of controlled substances for legitimate medical, scientific, research, and industrial purposes. The CSA also was established to help prevent the diversion of controlled substances destined for illegal purposes. The CSA mandates that there be a closed system of control for manufacturing, distributing, and dispensing controlled substances. To accomplish this, any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for their corresponding activity.

Pharmaceutical Controlled Substances

Pharmaceutical controlled substances are drugs that have a legitimate medical purpose, coupled with a potential for abuse and psychological and physical dependence. They include opiates, stimulants, depressants, hallucinogens, and anabolic steroids. These substances are divided into five schedules:

- Schedule I substances have the highest potential for abuse and have no accepted medical use within the United States. These substances may only be used for research, chemical analysis, or in the manufacturing process of other drugs.
- Schedule II – V substances have accepted medical uses and also have potential for abuse and psychological or physical dependence.

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Prescriptions for pharmaceutical controlled substances constitute a small percentage of the drugs prescribed in the United States—between 10 percent and 11 percent of all prescriptions written in the United States. Generally, for a pharmaceutical controlled substance to be dispensed legally, a prescription must be written by a practitioner licensed by the state where the practitioner is located and be registered with DEA to dispense these substances.

Although the number of pharmaceutical controlled substance prescriptions is a small portion of the overall total, the importance of ensuring a safe, secure, and accurate method for issuing legitimate prescriptions is increasingly important. According to a May 2007 report by the Kaiser Family Foundation, "From 1994 to 2005, the number of prescriptions purchased increased 71% (from 2.1 billion to 3.6 billion), compared to a US population growth of 9%."[1] Based upon these figures the number of prescription written for controlled substances in 2005 would have ranged from 360 million to 400 million.

With this increase in the number of prescriptions has come a disturbing increase in the abuse of prescription drugs. According to the most recent *National Survey on Drug Use and Health* (NSDUH), nearly 7 million Americans are abusing prescription drugs—more than the number who are abusing cocaine, heroin, hallucinogens, Ecstasy, and inhalants, combined. That 7 million was just 3.8 million in 2000, an 80 percent increase in just 6 years. Nearly 1 in 10 high school seniors admits to abusing powerful prescription painkillers. In addition, opioid painkillers now cause more drug overdose deaths than cocaine and heroin combined. As we discuss alternative technologies to ensure fewer drug interactions and higher quality, we should not forget that a prescription does not make these substances less dangerous. Additionally, black-market sales for prescription controlled substances are typically five to ten times their retail value. Profits generated from these illegal sales provide a strong incentive for continued diversion.

Pertinent Provisions of the CSA and DEA Regulations Pertaining to Prescriptions for Controlled Substances

In enacting the CSA, Congress sought to control the diversion of pharmaceutical controlled substances into illicit markets by establishing a "closed system" of drug distribution governing the legitimate handlers of controlled substances. Any regulatory action DEA takes to permit the electronic prescribing of controlled substances must meet existing statutory requirements and must continue to ensure the integrity of the "closed system" envisioned through the CSA.

The CSA currently mandates two different security standards for the prescribing of controlled substances, depending upon the schedule of the substance. The CSA requires that, except in limited emergency circumstances, a pharmacist may only dispense a schedule II controlled substance pursuant to a written prescription from a

[1] Kaiser Family Foundation, *Prescription Drug Trends*, May 2007 p. 2

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practitioner. For schedule III and IV controlled substances, a pharmacist may dispense the controlled substance pursuant to a written or oral prescription from a practitioner.

A prescription for a controlled substance may be issued only by an individual practitioner who is authorized to prescribe by the state in which he or she is licensed to practice and is registered, or exempted from registration, with DEA. To be valid, a prescription must be written for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice; a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment is not a prescription within the meaning and intent of the CSA, and the person knowingly filling such a purported prescription, as well as the person issuing it, is subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Longstanding DEA regulations specify that each written controlled substance prescription contain certain information including the practitioner's manual signature. This manual signature affixed to the prescription by the practitioner serves as formal attestation by the practitioner that the prescription has been written for a legitimate medical purpose and affirms the practitioner's authority to prescribe the controlled substance in question. The prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. Further, a corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by DEA regulations.

A prescription may be filled only by a pharmacist acting in the usual course of professional practice who is employed in a registered pharmacy. Except under limited circumstances, a pharmacist may dispense a schedule II controlled substance only upon receipt of the original written prescription manually signed by the practitioner. A pharmacist may dispense a schedule III or IV controlled substance only pursuant to a written and manually signed prescription from an individual practitioner, which is presented directly or transmitted via facsimile to the pharmacist, or an oral prescription, which the pharmacist promptly reduces to writing containing all of the information required to be in a prescription, except the signature of the practitioner.

Every prescription must be initialed and dated by the pharmacist filling the prescription. Under many circumstances, pharmacists are required to note certain specific information regarding dispensing on the prescription or recorded in a separate document referencing the prescription before the prescription is placed in the pharmacy's prescription records.

DEA requires the registered pharmacy to maintain records of each dispensing for two years from the date of dispensing of the controlled substance. However, many states require that these records be maintained for longer periods of time. These records must be made available for inspection and copying by authorized employees of DEA. This system of records is unique in that the prescribing practitioner creates the prescription, but the dispensing pharmacy retains the record.

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The signature requirement for written prescriptions for controlled substances provides DEA with reliable evidence needed to enforce the CSA in administrative, civil, and criminal legal proceedings. In criminal proceedings for violations of the CSA, the Government must prove the violation beyond a reasonable doubt. As the agency responsible for monitoring compliance with the regulatory requirements of the CSA, it is essential that DEA have the ability to determine whether a given prescription for a controlled substance was, in fact, signed by the practitioner whose name appears on the prescription. It is likewise essential that DEA have the ability to determine that a prescription that has been filled by a pharmacy was not altered after it was prepared by the practitioner. Further, because DEA relies on the records of these prescriptions in the conduct of investigations, DEA must also know that the prescription has not been altered after receipt by the pharmacy. Vulnerabilities at any point in this chain of custody will certainly compromise the Government's ability to successfully prosecute violations of the CSA.

The elements of the prescription that identify the practitioner (the practitioner's name, address, DEA registration number, and signature) also serve to enable the pharmacy to authenticate the prescription. If a pharmacy is unfamiliar with the practitioner, it can use the registration number to verify the identity of the practitioner through publicly available records. Those same records would indicate to the pharmacy whether the practitioner has the authority to prescribe the schedule of the controlled substance in question.

Requiring that the original documents be maintained in paper form serves to support both the accuracy and integrity of each record and, thus, the accuracy and integrity of the system of records as a whole. The availability of the original written and manually signed prescription provides a level of document integrity or provides physical evidence that the record has been altered: alterations of hard-copy records are usually apparent upon close examination. A forensic examination of a prescription can prove that a practitioner signed it or, equally important, that the practitioner did not sign it. The maintenance of the paper record at a pharmacy also ensures that state and local law enforcement agencies have access to records they need for investigations. In addition, the written prescription record ensures there will be a limited number of pharmacy employees who will have annotated the record and can testify that the prescription is, in fact, the prescription they received and dispensed.

All of these elements are present in existing federal law and regulations to ensure that prescriptions are legitimate, to deter the diversion of controlled substances prescriptions and the substances dispensed based on those prescriptions, and to provide federal, state, and local law enforcement with the tools necessary to detect diversion when it occurs. These same elements must be present in any electronic system for the same reasons.

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Other Governing Legislation

Besides the mandates of the CSA, regulations regarding electronic prescribing must be consistent with other statutory mandates and federal regulations. The Electronic Signatures in Global and National Commerce Act of 2000, commonly known as E-SIGN, was signed into law on June 30, 2000. It establishes the basic rules for using electronic signatures and records in commerce. E-SIGN was enacted to encourage electronic commerce by giving legal effect to electronic signatures and records and to protect consumers. E-SIGN provides that, with respect to any transaction in or affecting interstate or foreign commerce, a signature may not be denied legal effect solely because it is in electronic form. However, E-SIGN further provides that, where a statute or regulation requires retention of a record, and an electronic record is used to meet such requirement, federal, state, and local agencies may set performance standards to ensure accuracy, record integrity, and accessibility of records. Such performance standards may be specified in a manner that requires the implementation of a specific technology if such requirement serves an important governmental objective and is substantially related to that objective interest. DEA shares this vision as evidenced by its advance notice of rulemaking.[2]

In 2003, Congress enacted the Medicare Prescription Drug Improvement and Modernization Act, commonly referred to as the MMA. The MMA requires the Department of Health and Human Services (HHS) to develop standards for the transmission of electronic prescriptions for the Medicare Part D program. DEA recognizes that Congress and many in the healthcare industry want to encourage the shift to electronic medical records, including electronic prescriptions.

One of the considerations in support of the implementation of electronic prescriptions is the view that using electronic prescriptions, in lieu of written or oral prescriptions, could reduce medical errors that occur because handwriting is illegible or phoned in prescriptions are misunderstood as a result of similar sounding medication names. Another consideration is that, if prescription records are linked to other medical records, practitioners can be alerted at the time of prescribing to possible interactions with other drugs the patient is taking or allergies a patient might have. Electronic prescribing systems also can link to insurance formulary lists to inform the practitioner prior to prescribing whether a drug is covered by a patient's insurance.

As the committee is aware, 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 CSA.

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[2] Federal Register: March 5, 2001 (Volume 66, number 43)

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Means by Which Controlled Substances Are Diverted

Understanding the means by which controlled substances are diverted is critical to determining appropriate regulatory controls. One of the factors that contribute to the abuse of prescription controlled substances, as evidenced by the Partnership for a Drug-Free America's *Partnership Attitude Tracking Study*, is the perception by some members of the public that it is safer to abuse prescription substances than to abuse illicit substances. Diversion of prescription controlled substances can occur in a number of ways, including, but not limited to, the following:

- Prescription pads are stolen from practitioners' offices by patients, staff, or others and illegitimate prescriptions are written and forged.
- Legitimate prescriptions are altered to obtain additional amounts of legitimately prescribed controlled substances.
- Drug-seeking patients may falsify symptoms and/or obtain multiple prescriptions from different practitioners for their own use or for resale. In some cases, organized groups visit practitioners with fake symptoms to obtain prescriptions, which are filled and resold. Some patients resell their legitimately obtained drugs to earn extra money.
- Prescription pads containing legitimate practitioner information (e.g., name, address, DEA registration number) are printed with a different call back number that is answered by an accomplice to verify the prescription.
- Computers and scanning or copying equipment are used to create prescriptions for nonexistent practitioners or to copy legitimate practitioners' prescriptions.
- Pharmacies and other locations where controlled substances are stored are robbed or burglarized.
- Prescriptions are written for other than a legitimate medical purpose. Some practitioners have been convicted of knowingly writing prescriptions for non-medical purposes. Criminal organizations commonly referred to as "rogue Internet pharmacies" often employ practitioners to issue prescriptions based on on-line questionnaires from patients with whom the practitioner has no legitimate medical relationship.
- Controlled substances have been stolen from a pharmacy by pharmacy personnel. Legitimately dispensed prescriptions may be altered to make the thefts less detectable.

Given the risk of diversion, as well as the increasing extent of prescription controlled substance abuse in the United States, any system allowing the electronic prescribing of controlled substances must have sufficient safeguards to minimize risks and prevent further diversion. With proper controls, DEA believes the risk of diversion can actually be reduced through the use of electronic prescriptions. Among the essential elements of an envisioned system are the assurances that only DEA registrants electronically sign and authorize controlled substance prescriptions and that the prescription record cannot be altered without the alteration being detectable.

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Accordingly, a system that fails to provide standards for verification of the registrant's identity and authority to issue controlled substance prescriptions and/or that fails to ensure that alteration of the record is detectable would create new routes of diversion that could be even harder to prevent, detect, and investigate. Further, any system that does not have these safeguards will inhibit the Government's ability to meet its burden of proof in criminal, civil, and administrative proceedings. Systems lacking adequate controls would provide a plausible defense for a practitioner who would choose to divert these dangerous substances by simply denying that they authored and approved a prescription for a controlled substance. The Government's ability to refute their claim would be circumstantial or non-existent—hence the critical need for authentication, non-repudiation, and integrity of the record. In fact, without these standards we would create new avenues of diversion of pharmaceutical controlled substances and would place more Americans at risk for abuse, addition, and even death.

DEA's Regulatory Activities Regarding Electronic Prescribing

The CSA and DEA's regulations were originally adopted at a time when most transactions—particularly prescriptions—were completed on paper. The CSA mandates that many controlled substance prescriptions must be written; DEA regulations require that written prescriptions must be manually signed by the practitioner prescribing the controlled substance. In 1999, in response to requests from the regulated community, DEA began to examine how to revise its regulations to allow the use of electronic systems within the limits imposed by the statute and mindful that the records must be admissible in legal actions.

There is a strong foundation for electronic prescriptions that has been developed by HHS' Centers for Medicare and Medicaid Services (CMS) and industry. The challenge is building from this foundation a secure system for electronic prescriptions of controlled substances.

After an exhaustive review of current industry practices at the time, including practitioners' and pharmacies' use of computer technology, diversion concerns, and other issues, DEA developed three standards which it believed, and continues to believe, are critical in any electronic prescribing of controlled substances:

- Authentication: The system must enable a recipient to positively identify the signer and subsequently demonstrate to a third party, if needed, that the signer was properly identified.
- Nonrepudiation: The system must ensure that strong and substantial evidence is available to the recipient of the signer's identity, sufficient to prevent the signer from successfully denying having signed the data. This criterion includes the ability of a third party to verify the origin of the document.
- Record integrity: The system must ensure that the recipient or a third party can determine whether the document has been altered following signature.

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Because the law requires tighter controls for controlled substances than for other prescription drugs, an effective and secure electronic prescription system for controlled substances must minimize authentication concerns and maintain record integrity.

DEA is committed to its responsibilities under the CSA, as well as its obligations to issue regulations for the use of electronic prescriptions for controlled substances. DEA will continue our efforts to move the rulemaking for electronic prescriptions of controlled substances through the clearance process for submission to OMB pursuant to Executive Order 12866.

Conclusion

DEA is keenly aware that pharmaceutical controlled substances are vital tools for the medical community. DEA also is aware that various public and private entities are striving to leverage modern-day technology to streamline its business practices. DEA supports the responsible adoption of electronic prescriptions for controlled substances in a manner that will meet statutory obligations and minimize the risk of diversion. However, in the absence of appropriate controls, allowing electronic prescriptions for controlled substances would certainly exacerbate a growing epidemic of prescription drug abuse in the United States. It is essential that the rules governing the electronic prescribing of controlled substances do not undermine the ability of federal, state, and local law enforcement to identify and prosecute those who engage in diversion and put our citizens at risk.

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STATEMENT OF

TONY TRENKLE

DIRECTOR OF E-HEALTH & STANDARDS SERVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

ELECTRONIC PRESCRIBING OF CONTROLLED SUBSTANCES: ADDRESSING HEALTH CARE AND LAW ENFORCEMENT PRIORITIES

BEFORE THE SENATE JUDICIARY COMMITTEE

December 4, 2007

CMS

CENTERS for MEDICARE & MEDICAID SERVICES

Testimony of

Tony Trenkle, Director
Office of E-Health Standards and Services
Centers for Medicare & Medicaid Services

Before the
Senate Judiciary Committee
On
Electronic-Prescribing

December 4, 2007

Good morning Chairman Leahy, Senator Specter and distinguished members of the Committee. It is my pleasure to be here today to discuss the Centers for Medicare & Medicaid Services' (CMS) role in promoting widespread adoption of electronic prescribing (e-prescribing). The current medication prescribing process, which predominantly relies on handwritten prescriptions, is prone to errors.[1] Physicians and other prescribing health care professionals typically make drug-prescribing decisions using whatever information is known or readily available at the time they write a prescription. They often do not have a complete and accurate medication list or medical history for their patient and, as a result, they can miss potential contraindications or duplicate therapies.

It is estimated that each year some 530,000 adverse drug events take place among Medicare beneficiaries alone because of drugs negatively interacting with other drugs the patient is already taking, or insufficient information about the patient's medical history.[2] The Institute of Medicine (IOM) reported last year that more than 1.5 million Americans are injured annually by drug errors in hospitals, nursing homes and doctor's offices.[3] These negative drug events may require costly interventions in order to stabilize the patient, including hospitalization.

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[1] *See* Institute of Medicine (IOM). Preventing Medication Errors, July 2006. Retrieved from http://www.iom.edu/Object.File/Master/35/943/medication%20errors%20new.pdf.
[2] Field TS, et al. 2005. The costs associated with adverse drug events among older adults in the ambulatory setting. Medical Care 43(12):1171, 1176.
[3] IOM July 2006.

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The Benefits of Electronic-Prescribing

E-prescribing has the potential for improving beneficiary health outcomes. For providers who choose to invest in e-prescribing technology, the adoption also could improve quality and efficiency and could show promise in reducing costs by actively promoting appropriate drug usage; providing information to providers and dispensers about formulary-based drug coverage, including formulary alternatives and co-pay information; and speeding up the process of renewing medications. E-prescribing also may play a significant role in efforts to reduce the incidence of drug diversion by alerting providers and pharmacists of duplicative prescriptions for controlled substances.

E-prescribing has the potential to empower both prescribers and pharmacists to deliver higher quality care and improve workflow efficiencies. Typically, providers give a handwritten prescription to the patient or fax it to a pharmacy or other dispenser. Pharmacists can have a difficult time reading handwritten prescriptions and may have little or no information about the patient's condition for which the prescription is written. Contacting the provider by phone to clarify the prescription often results in delays for the patient and is time-consuming for both the provider and dispenser. According to some estimates, almost 30 percent of prescriptions require pharmacy callbacks.[4] This translates into less time available to the pharmacist for other important functions, such as educating consumers about their medications. A potential benefit of e-prescribing in preventing errors is that each prescription can be checked electronically – and quickly – at the time of prescribing.

In addition to the potential for saving time, the IOM has noted that widespread adoption of e-prescribing could eliminate thousands of adverse drug events each year.[5] For those individuals who require multiple medications, e-prescribing could help to promote medication therapy management and support care coordination across various providers. This could, in turn, decrease the financial impact of treating the results of adverse drug interactions. Additionally, having information about formulary alternatives could reduce patients' out-of-pocket costs, such as co-pays.

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[4] Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule. 70 FR 6256, February 4, 2005.
[5] IOM July 2006.

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Currently just 5 to 18 percent of providers are estimated to use available e-prescribing.[6] The technology required to electronically receive prescriptions is already in use by many pharmacies, however.

CMS Efforts to Promote Widespread Adoption of E-Prescribing

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directed CMS to establish standards to support a voluntary e-prescribing program for the Medicare prescription drug program (Part D). Although there is no requirement that providers write prescriptions electronically, providers that prescribe or dispense Part D drugs must comply with adopted standards when conducting electronic prescription transactions or seeking or transmitting prescription information for Part D drugs prescribed to Part D eligible individuals. CMS, based on National Committee on Vital and Health Statistics (NCVHS) recommendations reflecting industry and other stakeholder input, has taken an incremental approach to adopting final uniform standards for e-prescribing in Part D. This approach identified foundation standards that could be implemented by January 2006 and built upon through subsequent rulemaking. All standards will be consistent with the MMA objectives of patient safety, quality of care, and efficiencies and cost savings in the delivery of care.

CMS published a final rule establishing electronic prescribing foundation standards for the Part D program at the beginning of November 2005. Based on industry consensus and recommendations from the NCVHS,[7] the final rule identified three well-accepted standards that were ready for immediate implementation – "foundation" standards. The foundation standards took effect on January 1, 2006, and related to transactions involving: the communication of prescriptions and prescription-related information between prescribers and dispensers; eligibility and benefits inquiries and responses between prescribers and Part D sponsors; and eligibility and benefits inquiries and responses between dispensers and Part D sponsors.[8] The foundation standards were not pilot tested because there was already adequate industry experience with

[6] 70 FR 6256 at 6260 - 6261.
[7] See the September 2004 and March 2005 NCVHS letters to the Secretary of HHS (Thompson and Leavitt, respectively) at http://www.ncvhs.hhs.gov/040902lt2.htm and http://www.ncvhs.hhs.gov/050304lt.pdf.
[8] Medicare Program; E-Prescribing and the Prescription Drug Program; Final Rule 70 FR 67568, November 7, 2005.

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these standards. The publication of foundation standards in 2005 helped establish a basis for future e-prescribing implementation and interoperability.

In addition to publishing foundation standards in 2005, the Secretary also recognized six "initial standards" for pilot testing, consistent with the MMA's requirement. Those six initial standards address: formulary and benefit information; exchange of medication history; fill status notification (RxFill); structured patient instructions (SIG); clinical drug terminology (RxNorm); and prior authorization messaging.[9] The HHS e-prescribing pilot utilizes five pilot sites to test the initial standards. The pilot was set up to validate initial standards and their interoperability with existing foundation standards as well as to look at workflow issues associated with e-prescribing. CMS published a Report to Congress in April 2007, detailing the results of the pilot testing.[10]

On November 16, 2007, CMS published a notice of proposed rulemaking to adopt two of the six pilot tested initial standards (related formulary and benefit information, and exchange of medication history) as "Final Uniform Standards."[11] These proposed standards would supplement the foundation standards that took effect on January 1, 2006. The proposed formulary and benefit standard is intended to provide prescribers with information about a patient's drug coverage at the point of care. This may include information on formulary status and a list of alternative drugs that allow the provider in many cases to substitute a generic drug, thus saving the patient money. The goal is to enable the prescriber to take this information into account at the time of prescribing, which could reduce the amount of back-and-forth communication needed with the pharmacy or the health plan.

The medication history standard is the second standard CMS proposes to implement in the near term. This standard is intended to provide a uniform means for prescribers, dispensers, and payers to communicate about the list of drugs that have been dispensed to the patient. This standard is widely accepted and employed by those currently using e-prescribing.

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[9] Findings from the Evaluation of E-Prescribing Pilot Sites. Agency for Healthcare Research and Quality (AHRQ) Publication 07-0047 EF, April 2007, at viii.
[10] Id.
[11] 72 FR 64900.

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Pilot testing found that three remaining initial standards – Codified SIG, RxNorm, and prior authorization messaging – require additional work before they could be proposed as final uniform standards. The sixth standard – RxFill – is ready for Part D use but has not been proposed as a final standard due to an absence of marketplace demand at this time.[12]

At the end of the day, regardless of rulemaking, industry collaboration, or pilot testing, e-prescribing remains voluntary in Medicare and essentially throughout the health care marketplace. CMS is committed to continued testing and work with industry experts to advance the development of secure, scaleable and administratively feasible e-prescribing standards for use throughout the health care system. The challenge in moving forward is that the law does not treat all prescriptions the same. We look forward to addressing the challenges posed by controlled substances in future pilot programs.

Collaboration with DEA and Others

Concurrent with work to standardize e-prescribing in the Part D arena, CMS has been collaborating with the Drug Enforcement Administration (DEA) of the U.S. Department of Justice in recent years to identify and adopt commercially scaleable solutions that will allow for the e-prescribing of controlled substances consistent with the e-prescribing of non-controlled substances. The NCVHS held hearings in 2005 with testimony from various stakeholders including DEA, and published a recommendation letter to the Secretary in March 2005 in which they recommended that HHS, DEA, and state boards of pharmacy recognize "current e-prescribing network practices…as a basis for securing electronic prescriptions."[13] In July 2006, HHS and DEA co-sponsored a public meeting on e-prescribing of controlled substances and solicited input from stakeholders. At that time, CMS stated that we welcomed an opportunity to work jointly with DEA and industry to integrate DEA e-prescribing requirements related to controlled substances into mainstream industry e-prescribing products. CMS looks forward to partnering with DEA on this important step to combat fraud and harmful drug diversion, which

[12] 72 FR 64905
[13] NCVHS Letter, March 4, 2005, Recommended Action 1.1.

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also would help advance broader HHS and health care stakeholder goals in the public health arena.

Interagency cooperation, working closely together with all interested stakeholders, utilizing current platforms as much as possible, is vital to further growth in e-prescribing. Toward this end, the Administration supports pilot programs that could identify gaps in current e-prescribing security measures as a useful starting point. Pilots should be coordinated with other key health care stakeholders to ensure that mainstream solutions are developed.

Conclusion

Thank you for the opportunity to talk about CMS' role in promoting e-prescribing. We are committed to ensuring patient safety not only for the Medicare population, but for all Americans. CMS looks forward to continued work with DEA and others. I am happy to address any questions or concerns the Committee may have.

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Statement for the Record by:

Walgreens

"Electronic Prescribing of Controlled Substances: Addressing Health Care and Law Enforcement Priorities"

Committee on the Judiciary
United States Senate

December 4, 2007

Walgreens
1399 New York Ave., Suite 725
Washington, DC 20005
202-393-0414

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Walgreens thanks the Committee and Senator Whitehouse for convening this hearing on the electronic prescribing (e-prescribing) of controlled substances. As a national community pharmacy chain, our company actively supports the widespread adoption of e-prescribing technology and practices within the healthcare system. The numerous benefits to e-prescribing significantly improve patient outcomes. Increased patient safety, reduced costs, and enhanced relationships between prescriber and pharmacist are some of the advantages to a paperless prescribing system.

Benefits of E-prescribing

Technology gives physicians and pharmacists the ability to provide higher quality care in an efficient and effective manner. Several e-prescribing pilot programs have demonstrated better patient compliance, more clear and readable prescription documentation, and reliable authentication of prescribers. A recent study conducted by Walgreens and SureScripts using IMS industry data found an 11 percent increase in new prescriptions filled once a doctor becomes electronically enabled E-prescribing helps reduce adverse drug interactions while encouraging medication compliance—a win-win for the patient, provider, and physician.

Challenges to Widespread Adoption

Despite available technologies, only a small percentage of doctors choose to use e-prescribing because it currently is not allowed for controlled substances. Pharmacists have the capabilities and systems in place to process and fill prescriptions received electronically. According to NACDS, controlled substances account for around 11-13

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percent of all prescriptions. Yet, HHS estimates that just 5-18 percent of providers are using e-prescribing systems. A paper or oral prescription is the only legal current option for controlled substances. Providers are generally not interested in two different systems for prescribing and have been hesitant to adopt e-prescribing until it is allowed for all drugs.

Need for Federal Regulations

The pharmacy and prescribing community have been anxiously awaiting the Drug Enforcement Administration to promulgate regulations regarding the e-prescribing of controlled substances. Walgreens believes federal regulations would encourage widespread adoption of e-prescribing so physicians and clinicians can use a single system that allows them to prescribe the complete range of drugs their patients need. Utilizing existing technologies will maximize patient care at the prescribing and pharmacy level.

Walgreens pharmacists have seen firsthand the benefits of e-prescribing. Improved quality and efficiency in dispensing of medication and all pharmacy patient services is evident. With a paper prescription, a pharmacist frequently needs to phone a physician's office to verify if the handwriting is illegible or unclear. This process is time consuming for both the pharmacist and prescriber and would not be necessary with the electronic transmission of a prescription. Electronic prescriptions, unlike handwritten prescriptions, are legible, complete and have had a preliminary drug interaction, allergy and formulary check before arriving in the pharmacy. This allows pharmacists to spend more time consulting with patients and discussing their drug therapy.

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E-prescribing as a Law Enforcement Tool

In addition to improved patient safety, higher quality of care and improved workflow efficiencies, e-prescribing could be a valuable law enforcement tool. An electronic prescribing system can reduce diversion by tracking prescriptions, protecting from illicit prescribing, preventing doctor and pharmacy shopping, and providing helpful information to the law enforcement community.

Walgreens urges DEA to promulgate regulations for the e-prescribing of controlled substances. DEA needs to recognize that any electronic prescribing system is safer and more secure than a paper system. The lack of federal regulations regarding controlled substances is a barrier to widespread adoption of e-prescribing. The business and technical infrastructure to e-prescribing already exists, DEA simply needs to promulgate regulations to ensure complete utilization and realization of the full benefits to e-prescribing. Our healthcare system cannot afford to wait any longer.

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