2011 HOUSE HUMAN SERVICES

HB 1422

2011 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

HB 1422
January 31, 2011
Job #13821

☐ Conference Committee

Committee Clerk Signature Vicky Crabtree

Explanation or reason for introduction of bill/resolution:

To create an electronic prescription transmission.

Minutes: *See attached Testimonies #1-8*

Vice-Chair Pietsch: Called the hearing to order on HB 1422.

Rep. Robin Weisz: Introduced the bill. The title is about as much as I know about the bill. I agreed to sign onto this bill, having been involved in IT since I was elected back in 1996 and been on that committee forever and working quite a bit last session on the HIT legislation that came out of this body. I'm very supportive of what they are trying to do here. I do understand there may be some issues and questions that have to be resolved to ensure that this thing works properly for the hospitals and those that are involved. I think it makes sense in today's age from the standpoint of reduced errors, better efficiency and less time. It is amazing to me in some ways that the medical field is that far behind in the sense that we haven't gone in a much greater rate to electronic in all areas as far as the records and prescribing and transcribing etc. There are plenty of people here that can explain exactly what they are trying to do and how this work.

Paul Plofcham: Director of Government Relations for Pfizer. (See Testimony #1.)

Rep. Weisz: Explain where it talks about real time adjudication as far how that process would work under electronic prior authorization versus the current process?

Plofcham: Right now the physicians when they come across a drug that is placed on prior authorization, they have a paper form typically that they use. It has a series of steps established by the payer that the physician will go into the record and justify. These steps could include things for example, asking what prior therapies are. A step therapy if you will that is frequently involved where they would have to determine if they had been on another product prior to that. So what happens is the patient discusses a product with their physician, they get their paper prescription, they go to the pharmacist, they determine the product is on prior authorization and then that prior authorization process has to be worked through. Frequently the pharmacist will call the doctor or the doctor may already know and they have paper process going into play that then gets sent in and gets approval back for them. The reason this legislation asks for real time adjudication because we believe it is technically possible and it restores the decision making back to the patient and why you are

with your doctor. I mentioned that we believe it is technically possible, I say that to by sighting a couple of examples; some are not part of an e prescribing system and others are. For example, in South Dakota prior authorization is adjudicated electronically on the pharmacy side in their Medicaid system. When the patient shows up at the pharmacy if Medicaid has made a product prior auth, they have a process in place for them to adjudicate it with the pharmacist back into the Dept. of Health. I think they adjudicate seven out of 10 of them within 3 hours. Like real time. I sight examples where the Blue Cross of Tennessee and BC of New Jersey are putting into play now where that will allow real time and adjudication. BC of Tennessee and BC of New Jersey is a partnership of CVS and Surescripts are involved and both of them have people here to testify. The point of real time adjudication is so that when you are with your doctor and your chart is open and your history is there, you can talk to your doctor right then and there about what you are getting. Why the power of the electronic system is and why we believe it is possible is that all of us have computers at home. All of us have seen forms fill themselves out and in the electronic medical record, all of those boxes that the doctors are now required to check or those drugs that you are suppose to go get, they will all be in the electronic record and can self build most likely in a vast majority of cases. That is prior authorization and that is what we mean by real time adjudication.

Rep. Hofstad: Are there more than one platform being developed or are we focused in one particular platform? Tell me where we are in that process.

Plofcham: Yes. The direct answer is, there are many vendors who are developing packages to deliver e prescribing solutions.

Rep. Hofstad: As we go down this road then, is it the responsibility of the Health Dept. to find that platform and would we do that uniformly across the state so everyone is on the same system? Who pays for it? Where do we find the funds to implement this?

Plofcham: There are a lot of vendors. In my testimony I alluded to there are technology standards and those standards are being managed by the federal government. There is a health information technology coordinator and those are the folks that are certifying vendors that will be able to use patented technology scanners so all the systems talk to each other as part of this movement. In terms of what this bill is talking about in terms of some of these policy standards, and I will use the prior authorization as an example; this is one where the vendors would be required to develop it themselves. To deliver that capability which is a best practice capability existing in the marketplace. They would deliver that capability as part of the package and as part of the software packages that they roll out within the state. It is a required standard for the state.

Daniel Duletski: PharmD student intern representing the Board of Pharmacy. (See Testimony #2.)

Carlotta McCleary: Executive Director of ND Federation for Children's Mental Health. (See Testimony #3.)

Handed in Testimony

Susan Helgeland: Executive Director of Mental Health America of ND. (See Testimony #4.)

OPPOSITION

Jerry Jurena: President of the ND Hospital Association testified in opposition of the bill. (See Testimony #5.)

Doug Johnson: Vice-President of PBM/Payer Customer Relations for Surescripts. (See Testimony # 6.)

Rep. Weisz: How far away are we? Is this something near term or are we still several years out?

Doug Johnson: That is the $64,000.000 question isn't it? Is there an effort to NCPDP to investigate and work in collaboration with all the different state (inaudible) industry to create an appropriate standard? It is a very complex process I sense you all have a better grasp of now after hearing earlier testimony. In terms of timing, yes it is hard to predict, but we are years away, not months away from this just from a process. As a standards development organization NCPDP has very strict process and rules in terms of how new data, methods, types and standards are developed, are approved to committee through a ballet process and then adopted. Once we have adoption at a standards committee level, we still run into the marketplace adoption. Once you have the standard now the electronic medical record vendors, and the payers, can start developing to that standard. Not a trivial event and sometimes these software developed lifecycles are fairly lengthy. Can I give you a hard date, no I can't. But, we are still talking years before a standard is available.

Rep. Paur: You are based in Minneapolis, MN?

Johnson: Yes we are.

Rep. Paur: And MN adopted a (drops sentence).

Johnson: Minnesota has adopted some interesting requirements for e prescribing. However, electronic prior auth on the commercial side is not part of that. That is really this particular part of this legislation we are opposed to.

Rep. Hofstad: As you look into the future, would you consider that this electronic prescribing be part of the electronic medical record and does it all have to fit together to make this whole system work? Or can they stand apart?

Johnson: Electronic prescribing today is part of the fabric of healthcare IT. It is widely developed and adopted. Today we have 225,000 physicians nationally and 50,000 plus pharmacies, (inaudible) representing 240 million Americans already participating in the network for e-prescribing. E-prescribing is defined today from a work flow perspective is including patient benefit information, putting that in the hands of the physicians so they can make a clinically and economically appropriate prescribing choice and then transmit the script electronically. There will be further enhancements. Electronic prior authorization is a

perfect example that we all believe should be there. The issue here is timing. Electronic prescribing exists today and is well adopted across the entire country.

Rep. Paur: Do you know if there is anything in the present ND law that would preclude electronic prescription filing?

Johnson: No. E prescribing is legal in all 50 states. There are prescribers in pharmacies in ND today that are doing electronic prescribing. Prior auth identification exists. Meaning payers today using the current data standards can get an indicator to physician that a prior auth exists for a particular medication. And do that at the point of care versus the point of dispensing. It does not facilitate the automation around prior auth that is sought by this legislation. But, it is not being ignored from a payer perspective.

Rep. Schmidt: Given your position on electronic information technology, may I expect if this bill passes you would work diligently to accelerate the process?

Johnson: We have a dedicated regulatory team that would certainly do that however, as I mentioned we view electronic prior authorization favorably. We believe it is the right thing to do. Our concern is that the bill as written, if it became a requirement and the industry could not support it as identified in the bill today, it would by default bring e prescribing to a halt. People would be out of compliance with your new bill and I am not sure folks would want to go down that path. Would we work with you? As much as we can in terms of working within the standards framework. The network we have developed across the country is built upon the principle of neutrality and transparency and using data standards in all cases. We do not do anything preparatory. So when you talk about eligibility and formary benefit, medication history and new prescriptions and refill renewal requests; all of that is based upon accepted accredited standards organizations. It would be difficult for Surescripts as a network to support something outside that network or standards organization and promulgate that through the industry. What would then prevent other states from adopting something maybe slightly different? What would that structure look like for ND opposed to the rest of the country? So, I think there are some real challenges in pursuing that path.

Mike Ayotte: A pharmacist and Director of Government Affairs for CVS Caremark Corporation. (See Testimony #7.)

Rep. Weisz: Since you have been e prescribing since the early 90's. Why are we so far behind on national standards for the prior auth piece? It's not like prior auth hasn't been around for awhile either. What is holding it up or what's the problem or issues involved?

Ayotte: The federal government has passed a bunch of bills and they all have acronyms. The last one was MIPPA which was Medicaid Improvement for Patients and Provider Act. That act was really outside of the stimulus. First they came up with the stimulus bill to say listen doctors we are going to give you some money if you would e prescribe and use the electronic health records. What MIPPA says is a little bit different. It said, we are going to give you a little carrot if you e prescribe up to a certain level for Medicaid, Medicare Part B prescriptions. Then after 2012 we are going to take away money from you if you are not at that level. I think a lot of focus has been in that arena. I think the electronic prior

authorization arena is critical. It is truly a time issue for the doctor's office, patients, and pharmacies across the board. I don't know how long it is going to take to do, but we continue to push and volunteer to be the pilot because we believe it is important to do, but what the pilot showed us is that they needed to have a standard. That is the problem, getting everybody to agree to the standards because truly there are standard bodies that sit in DC and have representatives from every walk of the medical community and it is getting to agree to all the parts that need to be on it. Today prior authorization is generally manual. It can be some electronic, but it is rare and the requirements are different. What they are trying to do is build a platform that can be used across the whole country and across all of healthcare that would be able to support those types of activities. I think that is what the time issue is. We are in the process now, sharing our records with a large health system. We are getting closer. Technology moves at light speed. This one is just not moving as fast.

Rod St. Aubyn: Representing BC/BS of ND testified in opposition. We have two bills that are dealing with pharmacy at the same time and our pharmacy benefit manager is actually next door at the other bill hearing and is unable to testify. We have some concerns on this particular bill. Everyone else is already alluded to it already. It doesn't make sense to do a patch work of 50 different standards. There should be one national standard. We like the rest of you get really frustrated that it is taking so long to establish these standards and actually start doing a lot of this. We think it is in everyone's best interest to have some process. From an insurer's standpoint, our members are just ND. We have our members going south for a few months in the winter and people on vacation that utilize prescription services somewhere else. That's one of the reasons we feel there needs to be this national standard and we need to wait until they really do complete that process. As it stands with the bill as it is, we would oppose the current version of the bill.

Rep. Weisz: What's the bill number of the other?

St. Aubyn: I want to say 1418. It is the PBM audit bill.

Sheldon Wolf: Director of ND Health Information Technology provided information on the bill. (See Testimony #8.)

Harvey Hanel: Pharmacy Director at Workforce Safety and Insurance provided information primarily on the electronic prior authorization. The way it is written in this particular piece of legislation, WSI would not be able to comply with that. The majority of our medication prior authorizations really focus around issues of liability. Example: I get a call from the pharmacy that an anti-depressant has been prescribed for an injured worker. Liability on whether or not that depression is caused by the work injury has not already been determined. So there is no way we could do that in a real time environment. That requires getting the medical records from the prescriber and may also require getting past medical records to see if this is something that existed before the work injury. That extends across a number of different classes of medications that we have.

Vice-Chair Pietsch: Closed the hearing on HB 1422.

2011 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

HB 1422
February 7, 2011
Job #14075

☐ Conference Committee

Committee Clerk Signature Vicky Crabtree

Minutes:

Rep. Devlin: We will call the subcommittee together. I'm not sure where we are supposes to go with this and the Chairman won't be in for a little while yet. I think we have gotten several e-mails from various people interested in this bill. What I gave you was the Minnesota prescription drug statute that they were working on that was discussed in committee. They are going to have their prior authorization accessible now later than January 1, 2015. The National Council of Prescription Drug programs, there meeting on November 3, I'm just bringing you information on that when they talked about prior authorization workforce they said there XML transaction is ready to be tested. I have the name of someone who has worked with the NCPDP that I think will be able to answer some of our questions, but he is out until Friday. The note I got back from him said he could answer some things by e-mail. So I'm going to send him whatever questions we have. I wasn't planning on opening up for public testimony because the rest of the committee isn't here either. Nobody on either side is debating the need for e-prescribing. The real question is if prior auth can or should be done as part of e-prescribing. If we think it should or shouldn't, would mean some changes in the legislation. There is another bill in the Senate that probably provides another way for e-prescribing that looks to have more people on board with it. I believe you got note from Bob (inaudible) that explains SB 2122 and had other information from other people on that. Sheldon Wolf provided us some information on where the current state agency e-prescribing standards were, but were from 2008. I thought we needed more current information.

Rep. Schmidt: It is very difficult for me to understand when I haven't had any experience on what is being done now. I am being told that there is some degree of e-pharmacy at this present time. I have called my physician this morning and did ask to have a hands on session with that so I can make a better decision. They are to be getting back to me later today. I would like to at least rest until we get the opportunity to do that. I've ask the physician to provide me on their thoughts on both the Senate and House bills.

Rep. Devlin: The testimony from Howard Anderson and the Board of Pharmacy, but given by Daniel Duletski you should have that. You may want to review that again too. He provides good information of where we are in ND at this stage of the game. There are people here if you have questions for them I don't have any problems with that.

Rep. Holman: In my mind after listening to testimony, there was a conflict between the ability to do this now or that it will take longer. I think we got a mixed message on that. The

question I have deals with page 3 line c at the top. It basically says, "a prescriber can override", I'm not clear on the full intent of the meaning of that. That seems to conflict with the previous page on line c where it says, "nothing is designed to preclude or make more difficult the authorized or patient's selection of any particular pharmacy or covered drug". I probably need to percolate that for awhile.

Rep. Devlin: Maybe Howard can answer that.

(Howard speaking from the audience without a microphone and is inaudible.)

Dan Duletski: Intern with the State Board of Pharmacy.

Rep. Holman: Part c on page 3, the back page, on need to be clarified on the ability of the prescriber to override the medication of choice. I assume it means generic vs. brand.

Dan: As far as how that works in the prescriber's office, I am not sure how they override it. As far as I know they can prescribe as they want. If something does need a prior authorization it will come up when we submit to insurance through a claim. Say a prior authorization is required and then a paper copy must submitted by the physician.

Rep. Holman: The paper copy is part of what we are dealing with here.

Dan: The electronic prior auth I am sure would allow quicker authorization to the prescriber to the right (inaudible) to the insurance company doesn't want to cover.

Rep. Devlin: Can you tell us where e-prescribing is in the State of ND? What is our status and what will it be two years from now?

Dan: Can't answer that question for you.

Howard Anderson: Executive Director of Board of Pharmacy. Right now in ND vertically all of our pharmacies are prepared to accept electronic prescriptions and most do now. We are a little behind in what our physician systems are capable of transmitting at this point. Surescripts which you have heard mentioned is the company that is an intermediary in electronic prescribing. When a physician's system becomes certified by Surescripts that is they are capable of transmitting all of the required elements of information to Surescripts that is needed. Then Surescripts looks at those transmission and they can apply certain things from the third party payer that is based on what drug is on a particular insurance company's formulary. And, send messages back to the physician about that. Then they pass it onto the pharmacy that the patient has chosen for their prescription. What this bill is attempting to do is, so whatever the physician wants then the message goes back to Surescripts that I want this. There is a specific way the physician needs to do that. Right now the law in ND in 1902 says he must hand write the words when necessary. That is what you are seeing in SB 2122 now is to change that to fit e-prescribing. You mentioned those two lines on page 3, "able to be overridden by the prescriber so that the prescriber can prescribe the prescriber's medication choice for the patient." What this is doing is saying this system needs to have that and SB 2122 says specifically how that is accomplished. They aren't in conflict with each other, but SB 2122 clearly specifies in a

paragraph how that is accomplished. Seems like CMS is looking to require brand medically necessary. Our current law says, "brand necessary" so we are trying to match that.

Paul Plofcham: From Government Affairs for Pfizer. Regarding to questions on page 2 and page 3. This is all part of section 4 that has to do with alerts and messaging that comes to a physician. Not an issue about generic vs. brand prescribing. It is an issue where the doctor would (stops). Including alerts adverse events and access to form the information. This provides the protection so if a doctor were to receive an alert about an adverse event he or she could still override that based on their clinical judgment. It behaves the same way a paper process is. The physician can write any legal prescription based on their clinical judgment and these protections say they can also do that in the electronic world.

David Root: From Medco Health Solutions: A doctor doesn't need authority from the general assembly to write a prescription. The other issue we heard is that this doesn't have anything to do with blocking interdictions. Turn to page 2, number 2, "allow the prescription to be written through and neutral platform that does not use any means, program device including advertising, instant messaging and popup messaging to influence or attempt to influence through economic incentives or otherwise the prescribing decision of an authorized prescriber at the point of care. That specifically addresses interdictions so I would contend to the committee that section c on page 3 is incongruent with the attitude and desires of the rest of the legislation.

Rep. Devlin: Any other questions from the subcommittee of the people who are here today? Subcommittee, besides some update from the federal on where they are actually at what else do you need before we can make a recommendation to the committee?

Rep. Schmidt: Like I said, I would really like to sit at a computer with a physician and how it is being done now. I'm hoping to do that later today.

Rep. Holman: I need to work through the process here and see what we are changing. We are definitely moving into the electronic age and so we have to facilitate that. I want to make sure we are not changing more than our intent.

Rep. Devlin: As I said, I'm hoping to get some information back from the national, just so I understand where that is at a little better. We will talk about it this afternoon and then announce on the floor when we will meet again. Howard we will let you know when we are going to have another subcommittee meeting.

2011 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

HB 1422
February 8, 2011
Job #14195 (starting at 1:08)

☐ Conference Committee

Committee Clerk Signature Vicky Cratchree

Minutes:

Rep. Devlin: Madam Chair if I could give a little quick update on 1422 which is electronic description transmission. We are going to have a telephone conference call with a guy that is on the national board to answer all our questions whether it is feasible or not next Monday at 11:15 am in regular committee. There is a decided difference of opinion of the people bringing us the bill of what and cannot be done and this guy is the national expert on it and he is bipartisan and he will answer our questions. That is what the subcommittee set up.

2011 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

HB 1422
February 14, 2011
Job #14479

☐ Conference Committee

Committee Clerk Signature Vicky Crabtree

Minutes:

Chairman Weisz: Called the meeting to order for a conference call with Tony Schueth on 1422. Our subcommittee has been working on this, consisting of Representatives Devlin, Schmidt and Holman.

Rep: Devlin: The National Council of Prescription Drug Programs which is who this gentleman is with is a non-profit credited standards development organization. This is persons has been portrayed to be and I have no reason to doubt this; he is the expert on where we are with e pharmacy and with e prior authorization. He is supposed to be a completely neutral party I haven't been told by either party that he is not. That is his position with the national organization. Our hope was that he could at least tell us where we are at in the nation so we would know how far we could go with the bill in ND without compromising something.

Chairman Weisz: I thought it would be helpful if the whole committee was here for the conference call and you could ask questions if you had any and listen to what he has to say. Rep. Devlin have you and the subcommittee narrowed anything down?

Rep. Devlin: We've narrowed it down to the point that the we all understand that we are members of this committee and members of the subcommittee and that none of us want to be on the subcommittee. And, we have fully understand that we have done something to offend the chairman to get us on this committee. Other than that I don't know that we have narrowed it down much further.

Chairman Weisz: Thank you. It's nice to know that you have narrowed some of the subject matter down here.

Rep. Devlin: In all sincerity, the committee is really stuck and that is why we are making this phone call. There is people on both sides of this issue whether companies, representatives or whatever, that tell you on one side this will work perfectly and the other side will say this will never work and some are in between. Rep. Schmidt got a wonderful explanation from a doctor that I went through and I hope all of you went through. We still need to know where the national standards are at before we can move ahead. That is why we haven't done anymore than set this up at this stage.

Tony Schueth: Hello, Tony Schueth. (Pronounced Sheeth)

Chairman Weisz: This is Rep. Robin Weisz with the ND House Human Service Committee and we thank you for taking some of your time today to speak to us.

Schueth: You are more than welcome.

Chairman Weisz: If you could give us your background and your involvement in all of this and there will be several questions this committee will have.

Schueth: Sure. I am the CEO and managing partner of a consulting firm called, Point of Care Partner. This is a firm and it is www.pocp.com if you want to look me up. We are a health information technology, strategy and management consulting firm. If you look me up you will see that our client list spans the spectrum of companies that have a stake in the electronic prescribing. It includes health plans and payers, the federal government, technology companies, pharmaceutical manufacturers and even physicians and physician organizations. My background is that I have been involved in the electronic prescribing for going on 15 years now. I got involved in the mid 1990's and have stayed active in it. My firm has two active practices. One in what we call e medication management which is e prescribing and then some. And the other is e care management. I run the e prescribing and e medication management process. Over the course of those 15 years I worked at Merck Medco or Medco Health Solutions today a pharmacy management company. Before that I worked for a technology company that no longer exists. It was acquired by Web and D around 2000-2001 it is not in the marketplace and probably wouldn't have heard of it. Over the course of the years I have been the co-chair of NCPDP Group 11. NCPDP Is the National Council and Prescription Drug Programs and is a standard development organization and are different work groups that work on different types of things. The e-prescribing work group is work group 11 and I was co-chair of that for 2 or 3 years. I have also been the task group leader the NCPDP electronic prior authorization task group. It was in existence until mid year last year when they decided there wasn't enough activity around electronic prior authorization to keep that task group operating. I've worked on e-prior authorization under a contract with AHRQ and CMS for the University of Chicago. I've worked e-prior authorization as a consulting engagement. I've testified to NCVHS the National Committee on Vital and Health Statistics as well as other federal agencies and organizations. I think that gives you an understanding of my background. Is there is anything that you have any questions on?

Chairman Weisz: Thank you Mr. Schueth. Your comment that the task force on EPA (electronic payment authorization) that there was not enough activity to keep it operating. Can you expand on that?

Schueth: Before I jump into that I want to make one more thing clear. I am representing myself only. I'm not representing NCPDP or the task group. I'm not in a position to do that. And, I'm not representing any company or being compensated for this time. This is Tony Schueth and this is on my time that I'm having this conversation.

Chairman Weisz: Thank you and we appreciate that clarification.

Schueth: I was at NCPDP at the end of last week and someone had told them that someone from NCPDP was going to be speaking to your group here and I think it is

important that you understand that I am representing myself and not NCPDP or even the task groups. Prior authorization where it stands is this, we started the prior authorization group in 2004 and one of the things we worked on was we wanted to map the paper prior authorization path or workflow to standards to where they were either existing or where we might need to have standards. That is what the task group did initially. What we found was there were some standards that existed and some that needed to be built. At a very high level we started working on modifying the existing standards and building new standards. In 2006, the federal government under Medicare Drug Improvement and Modernization Act (MMA) commissioned AHRQ the Agency for Healthcare Research and Quality defunds five pilots around EPA and NCPDP we supported those pilots in that we said here are the standards that are out there and here's how they recommend that they be implemented. We were available as a sounding board if they had any problems or challenges. We were a multi-standard development organization task group. Even those we existed within NCPDP we still had members of our task group that came from other standard development organizations. There are a handful of standard development organizations in the industry that support healthcare. NCPDP is well known for its support of pharmacy transactions. It got its start with the claim transaction between the pharmacy and the payer. Long before the pilots and any of this happened they decided to build an e-prescription standard. We used the construct and resources of NCPDP to pull us all together. I was the task group leader. In 2006 these pilot standards were tested the outcome of that was a report back to AHRC and CMS. I was one of those five pilot tests. I was the project lead for one of those five pilot tests, specifically the one that was awarded to the Rand Corp. Dr. Douglas Bell was the principle investigator and I was the project lead. At the end of all of this, the five pilots came back and said, prior authorization needs more work. It is not ready for the industry to adopt it yet. Specifically where we thought it needed the most work, not speaking for the five pilots, but we the five pilots thought what needed the most work was (stops sentence) We felt like we were using four different standards and we thought that was awfully confusing to the marketplace. What we really needed was one standard. We recommended to AHRQ and CMS that they create just one standard. That was a little political because now some of these standard development organizations aren't going to be involved in that. That then was vetted through different standard development organizations by me then now I was contracted to AHRQ. I worked through a process and then we took back to the NCPDP task group the challenge of developing one standard. That standard was developed in 2009. There is a standard and that is true there is one for prior authorization and that standard was validated by NCPDP and approved, but it was not approved as a standard a draft. A standard that could be pilot tested. That standard that was approved to be pilot tested is now available to NCPDP members, but the challenge we have is that no one to date has stepped forward and pilot tested that transaction. It is important for you folks to know because you don't live my world, health information technology world. If you are going to pilot test a transaction the first thing you have to have money and not an insignificant amount of money. The second thing they have to have is an organization of key stake holders and almost like a principle investigator like we had in 2005. They have to have an infrastructure of key individuals involved in this and companies. If someone were to start today it would take them approximately and it depends on how long the duration of the pilot test would go. Often things are pilot tested over an entire year. From my experience with Rand in 2006 and other projects it is going to talk about a half year to get something launched. If you run it for a year, there is a year of live transactions and then you have about a half a year of analysis

and evaluation of what worked and what didn't. If someone launched a pilot today you would be looking at 2 years down the road before the standard was ready. Then you have a process that NCPDP follows in order to approve a standard. You have 2 years of pilot testing and then 6 months of validating and debate and those types of things at NCPDP. You are looking at 2 ½ years before standard would be ready for the marketplace depending on how long your pilot is.

Chairman Weisz: My question is, when you came up with this standard that was developed in 2009 was there any response on why someone hasn't taken it and gone forward to start the process? Is CMS not interested in funding this?

Schueth: CMS has a lot of priorities right now with meaningful use and those kinds of things. I was never officially told by CMS one way or another, but they never did step forward to fund the pilot and that is a fact. To date neither has any private entity. It is possible I am not aware, but I am not aware of a pilot test that has been concluded. I have heard rumors of some that maybe in the process of getting started. In my opinion it is two reasons why it has not happened. One it is not an insubstantial amount of money to invest the pilot test of this magnitude. This is a transaction that will touch a number of different stake holders. It is going to originate on computer software in a doctor's office and it is costing them some software. It is going to be transmitted more than likely through an intermediary to a payer organization. Now there is an intermediary and a payer organization and if you only have one it keeps it simpler, but the more payers you get involved the more complex it gets and the more entities you get involved in standardized testing the more complex it gets. I believe there are two reasons that this hasn't happened. One is there is a funding challenge. We all know what happened in our society since the end of 2008 and remember I said the standard was available in 2009. Not that healthcare has been impacted as other elements of our economy, but it certainly is a factor. The other thing I think is that we in health information technology have had our hands full with meaningful use, which think the committee is well aware of. It has been described as sucking the air out of the room. It is so big and monumental and the impact of it is so grand that it is requiring an amazing amount of resources, creativity, and ingenuity in order to meet the requirements from the federal government around meaningful use.

Rep. Paur: My understanding is that there is no universal standard for electronic prior authorization?

Schueth: That is correct, but there is a standard that is validated that can be pilot tested and it would be 2 to 2 ½ years before that standard would be ready for widespread adoption nationwide.

Rep. Porter: Without a standard to run with and until the standard is adopted and created across the industry, there seems to be a lot of bits and pieces popping up in legislation calling for bans on pop ups, advertising and those kinds of things. It is to stop some marketing strategies from companies selling or developing the software. In our look at this I think this is a good way to go to help it work between the healthcare provider and the pharmacy, but as we look going forward, do we take the steps that other states have taken in order to stop some of the other practices inside of this industry?

Schueth: I'm not sure I can answer that without interjecting opinion. What I will say is, there is a lot of (stops sentence). Some of the key stake holders in this industry have contractual language that doesn't allow certain things to happen like pop ups. There is also a factor of anything that slows down the physicians as he or she is prescribing has been really shied away from. We have had a substantial challenge to date with getting physicians to adopt. I told the committee that I have been involved in electronic prescribing for 15 years. A person who works with me actually built one of the first e-prescribing systems for the Veteran's Administration in the 1980's. If you think about it we have for more than 30 years have been trying to get e-prescribing adopted in this country. There all kinds of reasons why that hasn't happened. One of things that every stake holder and e-prescribing is concerned about is anything that will impede adoption and use by a physician. They avoid anything that will slow them down. That is all I can say about that.

Rep. Devlin: I didn't realize there wasn't enough activity to keep the task force going. Is there something out there that we can grab a hold of that says 3 or 5 years from now that e-prior authorization can be a doable thing for the states?

Schueth: Well, the technology is out there. It is not a matter of technology. It is possible that prior authorization can be done in a non-standard way, but I don't know if that serves anybody. We all believe and certainly the MMA, it was all about making sure that there are standards in place in Healthcare IT. That is why the emphasis was on first the National Committee of Vital and Health Statistics. First they wanted hearings. They wanted to hear from industry experts on all sides of the equation. They listened to all different stakeholders, NCPDP, Surescripts was in existence at that time, but hadn't merged with our hub yet. They listened to both of them and their competing intermediaries. Listened to the federal government and pharmaceutical manufacturers, technology companies and listened to me. It the short term it is possible to do prior authorization without it being standardized, but there are concerns that I think that people would have in it not being a standardized transaction. The reality is there is a standard in the industry to do this it just needs to be pilot tested.

Rep. Hofstad: As we move forward with this standardization process, are we impeded or helped from the affordable healthcare act? Is this something that will help us or hinder us? Are we out ahead of the healthcare act? Or is it a process by which the healthcare act will set some of those standards?

Schueth: That's an interesting question. In my opinion this health reform will help increase adoption of technology. There are some things in there that have a lot of promise. As it pertains to e-prescribing, there really isn't a lot in the health reform about e-prescribing. Most of e-prescribing goes back to ARRA the American Reinvestment and Recovery Act. Where the HITECH Act has set aside $29 billion to encourage adoption of electronic health records and e-prescribing is part of that. It is part of meaningful use and part of stage one that they have already announced. They have a draft for stages two and three which the industry is in the process of sort of responding to. So, are you ahead of the curve? The honest truth is I haven't study the bill that is before your committee thoroughly. I did skim it. The e-prior authorization elements that we are talking about here are not in ARRA or in health reform either. I think in some ways with prior authorization some can make the case that you might be a little ahead of the curve. E-prescribing is in it and it is

being encouraged as part of all that, but not a lot of details under "e-prescribing" and what you have done, at least in my scan of the bill, you have put some details underneath that. I don't know if it is fair to say you are ahead of the curve as much as you are filling in some of the details. E-prescribing is being encouraged by ARRA and by the industry. If you retained me as a consultant, one of the slides I would show you is the adoption curve and we are on a path for dramatic increase of adoption right now. Dramatic being defined as by the end of 2011 and early 2012 we expect 50% of the doctors in the country to be prescribing electronically. The federal government I believe is shooting for 2015 or 17 with 90% of doctors. We are a little more conservative than that with our analysis, my consulting firm. Another role I play is the project manager for the Southeastern e-prescribing initiative or SEMI. That is a private coalition of General Motors, Ford Chrysler, BC/BS of Michigan, Health Alliance Plan, Medco and Care Mark, the PBM's. What we have seen in the State of Michigan is we are now #2 in the country after Massachusetts as far as adoption of e-prescribing.

Rep. Devlin: I understand you that you have been working 30 years in e-prescribing and some of us are afraid we might be having this conversation about e-prior authorization 30 years from now. Is there anything the states can do to push it along? My thought is when MN passed a bill that said no later than January 1, 2015 e-prior authorization request must be assessable and submitted and so on and so forth; does efforts by the state help the establishments of the national standards on a quicker time table?

Schueth: In general I think it does. One of the things my consulting firm does is produce a centennial event alert. And for our clients when something happens that materially impactful on the business from the HIT perspective, we give them a heads up an alert. We gave them a heads up on what happened in MN. There were a lot of hearings and a number of testimonies. I personally spoke to the State of MN on two separate occasions and gave them a very similar testimony that I have given you today. I sat in on some of the some of the committee meetings and sent my employees to sit on others and it certainly encourages the industry to move forward. There are things that happen on the federal level. But, I do believe that having realistic expectations and timelines are important. When MN first came out they were going to know what the standard 1-1-10 and be alive by 1-1-11 and the industry spent all its time and resources convincing MN that that was unrealistic. I don't think that was as productive. But, now that they have a reasonable date out there that is a reasonable distance in the future; I think that is valuable. Any player that is in your state that sees that 2015 date, they are going to have time to figure it out and time to budget and time to pilot test if they aren't already. They will have time to pilot test and it will position them to meet that time frame.

Chairman Weisz: Thank you Mr. Schueth and if you have any final comments for this committee. We really appreciate you taking your time with us today.

Schueth: Mr. Devlin you had in an e-mail something about you heard things like this will kill e-prescribing adoption or maybe impede the ability for your doctors to earn meaningful use. Is that correct?

Rep. Devlin: Yes, that is probably true. We hear a lot of things from the different players in this thing and if somebody says it is good I can guarantee somebody else will tell me it is the worst thing in the world. Yes, I think we did hear that.

Schueth: From will it impede the adoption of e-prescribing; if there are elements to the bill that are required in a time frame that the industry can't meet, that would make those two statements true. If however, there are realistic expectations around certain elements of what the industry can do then I don't agree with that. For example with prior authorization we really need a little bit more time to have standardized prior authorization. We could do something non-standardized in the short term. But again, that might be counter-productive. It certainly is counter-productive the way the government has been trying to encourage the adoption of e-prescribing. As far as meaningful use the same could be said. If the doctor because there are certain requirements of he or she that the industry is not able to do in the timeframe and then they can't prescribe mechanically, then that would impede their ability to get meaningful use. Meaningful use phase one, there is a menu item and core item. One of the core items is that they have to write a certain number of prescriptions electronically and attest to that fact. It depends on the context. When you told me those things I was a little bit taken aback, but it all depends on the context that those statements are considered in. Does that help?

Rep. Devlin: Yes it does and I understand exactly what you are saying and we appreciate your time here today.

Schueth: After your discussion if you have any additional questions and if someone wants to follow-up with me directly, I would be happy to help in any other way.

Chairman Weisz: Thank you very much Mr. Schueth, we really appreciate your time you took with us today and it is very possible there may be more questions following. Thank you.

Schueth: Glad to be of help. Take care. Bye Bye.

Chairman Weisz: Bye. Ok committee, any questions now that he is off? The subcommittee, Rep. Devlin are you planning to meet this afternoon?

Rep. Devlin: I'm sure we will. We will announce it on the floor.

Chairman Weisz: The subcommittee will meet and if anybody's got any input after listening to Mr. Schueth, I thought it was quite informative actually, you can relay it to the subcommittee. If you are interested in the subcommittee, listen on the floor for the announcement.

2011 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

HB 1422
February 14, 2011
Job #14504

☐ Conference Committee

Committee Clerk Signature Vicky Crabtree

Minutes:

Subcommittee meeting on HB 1422

Rep. Schmidt: ... exists to do it. Seeing rapid adoption of e-prescribing is what they are doing. States doing it with help of accelerating to get it done. Those are what I wrote. My thoughts are based on what we heard this morning from the gentleman who I think is probably very much in the know. He said, I've got four items I believe support it. I did go through my physician's note and he said we should be amending Section 3. I gave my copy to Rep. Louser and he did not give it back to me, so I don't have my written copy from the physician. I thought the physician did an excellent job of outlining a lot of the issues with it from his perspective. That was Dr. Bob Rosli.

Rep. Devlin: As much as I'd like ND to have the one technically reasonably done one in the nation, that probably isn't too realistic at this stage of the game. Where do we go from here? I'm not willing to kill this bill. I think we need to keep it alive to negotiate some other stuff later. I don't know that anybody is really other than the date that they have a real problem with what Minnesota has did to put some dates in there. They had 2015 prior auth must be assessable whether that is doable. I talked to a couple other members of the committee and they thought it would be further ahead to move that up to late 2013 so we would still have the legislation session in between if we wanted to do anything with it. It would be easier to hog house this bill if we just want to do what Florida did about e-prescribing. To my knowledge no one has any objections to. Then add in the MN language. It would be pretty easy to do.

Rep. Schmidt: I would support that sir. I also want to make note that my physician did say that the tier level that BC/BS has, has been very beneficial to the way he delivers his medications.

Rep. Holman: Do you want me to move the amendments?

Rep. Devlin: I don't know if we need to (stops). I think that's the best we can do to present to the committee and then they can fight it out. I don't think anyone is going to object to this.

Rep. Holman: I move the suggested amendments. With the change that on the 4th line up from the bottom we change the date to August 1, 2013. (See attachment #1.)

Rep. Schmidt: Second.

Voice Vote: Motion Carried

2011 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

HB 1422
February 16, 2011
Job #14593

☐ Conference Committee

Committee Clerk Signature Vicky Crabtree

Minutes:

Chairman Weisz: Called the meeting to order on HB 1422. Rep. Devlin is handing you out amendments on HB 1422. (See attachments #1-3.) There should be two sets of amendments. I will ask him to report on the subcommittee.

Rep. Devlin: The subcommittee met on this and half way agreed on what we were going to do. We really liked what Minnesota had done and wanted to keep that part of the language alive. Some of us liked the language in the Florida bill. We handed out that sheet before that had four states that adopted something. Essentially both of these bills are hog house. They get rid of all the language you have been hearing about and these are essentially the bills. The 01.1003 is the Minnesota language and had a 2015 date. It was suggested by this committee to go down to 2013 which would be after the best legislative session. And the one that the drug prior authorization must be, request must be accessible and submitted by a healthcare provider and must be accepted by group purchaser electronically through secure transmission and does not include a fax. The second part was who they would report to. Because our situation is different than Minnesota's and visiting with Rep. Weisz, he said the health information technology advisory committee would probably be the one that should work through that with the State Department of Health. We report to them by January 2012 on how to best standardize drug prior authorization requests transmission between providers and group purchasers. The 01.004 has that Florida language that says in Section 2 of the bill you can't use pop ups and other things to interfere with the prior authorization between the doctor and the patient. That is essentially the difference the two bills. I don't think the subcommittee is hard and fast on either one of them. The longer one will be more controversial among some of the members, but it doesn't mean it isn't the right thing to do.

Chairman Weisz: Explain a little more what subsection 2 does on the 04 amendment.

Rep. Devlin: Essentially the intent in the original bill was trying to bring the prior auth that is available now through written form to electronic means. A number of us have had a problem of getting between the doctor and the patient. This is saying you can't use economic incentives or other ways to get doctors to prescribe a certain generic or brand name drug.

Rep. Paur: I was wondering why this is under Chapter 23-01. The SB 2122 deals with electronic prescriptions and is under Section 3 and 4 of section 19-02.1-14.1 of ND Century Code. Why do we have it under a section that doesn't deal with electronic prescriptions?

Rep. Devlin: According to (inaudible) when we were doing a new section of the law that it would fit better under 23-01. That is what she told us.

Chairman Weisz: That would be my assumption that L.C. (drops sentence). We normally don't tell them what section it should go in. 23-01 is health and safety and that's the general chapter. The State Dept. of Health and that is probably the rationale. 19-02 is strictly definition.

Rep. Devlin: It may be just because of Section 2 specifies the Dept. of Health working together on it. That may be why she thought it should go there.

Chairman Weisz: I'd say it fits better under 23 than in 19 and 19 doesn't have anything to do with electronic prescribing. It is in there because it has to do with the pharmacist that's prescribing. It is dealing with prior auth more than just the act of a pharmacist prescribing and that's why she put it in 19.

Rep. Porter: I understand this is a complicated issue and it is going to happen at a point and time whether we get our arms around it prior to it happening or not. As I look at the language in the two bills I'm tending to lean towards 04 version. I think if we are going to pass something out of the House and the conference committee and even during the next legislative session. It needs to encompass that area also. Some of the alerts that may pop up like there is another generic medication that could save the patient $100 is not a bad alert. I don't think we should allow pushing one direction or another. This is prior authorization and they asking an insurance company for the ability to prescribe a certain medication. The effective date is 2013 on everything that it gives everybody the opportunity and ability to fine tune and get this where it does fit into a nationwide scheme of things. It also puts us on record of what we do and don't like.

Chairman Weisz: I looked at that subsection 2 also and I think the language says, the alerts must be supported so it doesn't eliminate the alerts. As far as the date I think the rationale is that we are going to be back here. It does send a message to both the federal and vendors that we want to go forward with prior auth. With the process of prior auth itself that is a separate issue than doing it electronically.

Rep. Holman: As I look at Subsection 2 I think it is important for us to read that second, third and forth lines without the extra things in there. "To communicate a prescription to a pharmacy (stops) may not use any means or permit any other person to use any means" and then need to go right to "influence or attempt to influence". We have words in there that are specific to specific actions. Basically, "may not use any means or permit any other person to use any other means to influence or attempt to influence the prescribing practitioner at that point of care". That is really the just of that sentence. The other words are just adding examples.

Rep. Devlin: I move the amendment 01004.

Rep. Schmidt: Second.

Rep. Paur: I feel uncomfortable being proactive here. I would rather be reactive on this stuff and probably will vote no on the amendment and the bill

Voice Vote: Motion Carried. Amendment Adopted.

Rep. Devlin: Do Pass as amended.

Rep. Schmidt: Second.

Rep. Louser: At what point is there going to be alerts or advertising or pop ups if not triggered by the input? That last sentence where it says, "any alert must be consistent with food and drug administration"

Chairman Weisz: Obviously that is what triggers them. What it is saying is that you can't have a alert that says you should use this drug because we think it is blah, blah, blah. It is not prohibiting alerts. It is prohibiting the advertising and trying to move the physician in a specific direction.

Rep. Anderson: Is price going to be part of that information?

Chairman Weisz: Rep. Devlin can you respond to that?

Rep. Devlin: (Inaudible)

Rep. Porter: I would venture a guess that pricing could be part of it, but the attempt to influence through economic incentives like rebates would not be. ND Medicaid knows what the formulary price is already. BC/BS knows which medications are approved to prescribe.

Roll Call Vote: 11y and 2 n
DP Carried

Bill Carrier: Rep. Devlin

#1

11.0684.01003
Title.

Prepared by the Legislative Council staff for
Representative Devlin
February 15, 2011

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1422

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to create and enact a new section to chapter 23-01 of the North Dakota Century Code, relating to electronic drug prior authorization standards; and to provide for a report to the legislative management.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new section to chapter 23-01 of the North Dakota Century Code is created and enacted as follows:

Electronic drug prior authorization and transmission.

Effective August 1, 2013, a drug prior authorization request must be accessible and submitted by a health care provider and must be accepted by a group purchaser electronically through a secure electronic transmission. For purposes of this section, a facsimile is not an electronic transmission.

SECTION 2. ELECTRONIC DRUG PRIOR AUTHORIZATION STANDARDIZATION AND TRANSMISSION - REPORT TO LEGISLATIVE MANAGEMENT. During the 2011-12 interim, the state department of health and the health information technology advisory committee shall work together to establish an outline on how best to standardize drug prior authorization request transactions between providers and group purchasers. The outline must be designed with the goal of maximizing administrative simplification and efficiency in preparation for electronic transmissions and alignment with standards that are or will potentially be used nationally. By January 1, 2012, the state department of health and the health information technology advisory committee shall provide a report to the legislative management regarding the outline on how best to standardize drug prior authorization request transactions between providers and group purchasers."

Renumber accordingly

Date: 2-14-11
Roll Call Vote # 1

2011 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1422

House HUMAN SERVICES Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken: ☐ Do Pass ☐ Do Not Pass ☐ Amended ☒ Adopt Amendment

☐ Rerefer to Appropriations ☐ Reconsider

Motion Made By Rep. Holman Seconded By Rep. Schmidt

Representatives	Yes	No	Representatives	Yes	No
CHAIRMAN WEISZ			REP. CONKLIN		
VICE-CHAIR PIETSCH			REP. HOLMAN		
REP. ANDERSON			REP. KILICHOWSKI		
REP. DAMSCHEN					
REP. DEVLIN					
REP. HOFSTAD					
REP. LOUSER					
REP. PAUR					
REP. PORTER					
REP. SCHMIDT					

Total (Yes) _____ No _____

Absent _____

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

Voice Vote

Motion Carried

11.0684.01004
Title.02000

Prepared by the Legislative Council staff for
Representative Devlin
February 16, 2011

VR
2/16/11

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1422

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to create and enact a new section to chapter 23-01 of the North Dakota Century Code, relating to electronic drug prior authorization standards; and to provide for a report to the legislative management.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new section to chapter 23-01 of the North Dakota Century Code is created and enacted as follows:

Electronic drug prior authorization and transmission - Limitations.

1. Effective August 1, 2013, a drug prior authorization request must be accessible and submitted by a health care provider and must be accepted by a group purchaser electronically through a secure electronic transmission. For purposes of this section, a facsimile is not an electronic transmission.

2. Effective August 1, 2013, electronic transmission devices used to communicate a prescription to a pharmacist may not use any means or permit any other person to use any means, including alerts, advertising, messaging, and popup advertisements, to influence or attempt to influence through economic incentives or otherwise the prescribing decision of a prescribing practitioner at the point of care. Such means may not be triggered by or be in specific response to the input, selection, or act of a prescribing practitioner or the prescribing practitioner's staff in prescribing a certain pharmaceutical or directing a patient to a certain pharmacy. Any alert, advertising, messaging, or popup advertisements must be supported by scientific evidence and must be consistent with the federal food and drug administration regulations for advertising pharmaceutical products.

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Renumber accordingly

Date: 2-16-11
Roll Call Vote # 1

2011 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1422

House HUMAN SERVICES Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken: ☐ Do Pass ☐ Do Not Pass ☐ Amended ☒ Adopt Amendment

☐ Rerefer to Appropriations ☐ Reconsider

Motion Made By Rep. Devlin Seconded By Rep. Schmidt

Representatives	Yes	No	Representatives	Yes	No
CHAIRMAN WEISZ			REP. CONKLIN		
VICE-CHAIR PIETSCH			REP. HOLMAN		
REP. ANDERSON			REP. KILICHOWSKI		
REP. DAMSCHEN					
REP. DEVLIN					
REP. HOFSTAD					
REP. LOUSER					
REP. PAUR					
REP. PORTER					
REP. SCHMIDT					

Total (Yes) _____ No _____

Absent _____

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

ADOPT version 04

Voice Vote
Motion Carried

Date: 2-16-11
Roll Call Vote # 2

2011 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1422

House HUMAN SERVICES Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken: ☒ Do Pass ☐ Do Not Pass ☒ Amended ☐ Adopt Amendment

☐ Rerefer to Appropriations ☐ Reconsider

Motion Made By Rep. Devlin Seconded By Rep. Schmidt

Representatives	Yes	No	Representatives	Yes	No
CHAIRMAN WEISZ	✓		REP. CONKLIN	✓	
VICE-CHAIR PIETSCH	✓		REP. HOLMAN	✓	
REP. ANDERSON	✓		REP. KILICHOWSKI	✓	
REP. DAMSCHEN	✓				
REP. DEVLIN	✓				
REP. HOFSTAD	✓				
REP. LOUSER		✓			
REP. PAUR		✓			
REP. PORTER	✓				
REP. SCHMIDT	✓				

Total (Yes) 11 No 2

Absent _____

Floor Assignment Rep. Devlin

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1422: Human Services Committee (Rep. Weisz, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (11 YEAS, 2 NAYS, 0 ABSENT AND NOT VOTING). HB 1422 was placed on the Sixth order on the calendar.

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to create and enact a new section to chapter 23-01 of the North Dakota Century Code, relating to electronic drug prior authorization standards; and to provide for a report to the legislative management.

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Renumber accordingly

2011 SENATE INDUSTRY, BUSINESS AND LABOR

HB 1422

2011 SENATE STANDING COMMITTEE MINUTES

Senate Industry, Business and Labor Committee
Roosevelt Park Room, State Capitol

HB 1422
March 9, 2011
Job Number 15150

☐ Conference Committee

Committee Clerk Signature Era Liebelt

Explanation or reason for introduction of bill/resolution:

Relating to electronic drug prior authorization standards

Minutes: Testimony Attached

Chairman Klein: Opened the hearing on House Bill 1422.

Representative Weisz: He brought the bill. He said it is basically an e prior authorization bill. They are trying to move the industry beyond e prescribing but to go into electronic prior authorization. He said the federal government has established guidelines for meaningful use. The whole healthcare industry is moving to electronic records. He said it saves time, efficiency and accuracy improves. He said this bill takes it to the next step. He said that they had already heard that maybe the industry isn't ready yet to do e prior authorization today and that standards weren't in place. They put dates in the bill so they will be moving to that direction and giving them two years to get there. It also states in the bill that they will have a reporting requirement that says they have to report to an interim committee to see how the progress is going; the date is August 1, 2013. This is bill is about the electronic transmitting of prior authorization. He said nothing in the bill changes the process of prior authorization. He said there is discussion about the process being changed and more name brand drugs being sold over generic. He said he would argue if this bill changes then the process wasn't right to start with. The discussion should be about the health care industry moving to an electronic system all the way through. He said there is a standard in place for this it will be around two years before the entire prodigal within the standard is established.

Chairman Klein: Stated they could continue if new information became available that had scientific bases that could be a message that is sent on.

Rep. Weisz: He said that is his understanding.

Chairman Klein: Asked if they could still be denied on the other side.

Rep. Weisz: Said that they have to have the reasons to do it. Then it is either the process itself isn't right or we don't have prior authorization defined properly.

Paul Plofchan, Government Relations and Director for Pfizer of North Dakota: Written Testimony (1).

Senator Andrist: Asked how this would work compared to the paper generation. When a doctor wants to be brand specific he has a box he can check, when he is e prescribing he will still have that box so he can request brand specific?

Paul: Said sure. The issue about being able to request brand specific when there is a generic is not in 1422. There are procedures for doing that in North Dakota and he believes that there are other bills that will try to address that. The question about how it works between paper and the electronic process. He said now when the doctor is using an electronic prescribing system they will see the formulary and the alert and message system. When the doctor is selecting a product from that formulary he will see electronically what his choices are. What the alert and messaging says is you can't send a message suggesting another brand. On the prior authorization part, if it requires a prior authorization she will send it not knowing if it is approved or the other option is to go to a paper process and fill out a form and wait for an answer. It is a separate process now and this bill wants it to be incorporated. It just talks about the messaging that can be sent.

Chairman Klein: Said what they need to keep separate is the difference between the electronic prescriptions and electronic prior authorization.

Paul: This is true. He said that he would like to clarify that there are components in the bill that address alerts and messaging on electronic prescriptions. They are trying to automate the electronic prior authorization process to enable and advance electronic prescribing.

Chairman Klein: There is a notion that this is a Pfizer issue because your name brands are coming off of their trademark. There has to be other companies out there that are excited about doing this electronically. He asked how he would respond to the fact that they are getting this Pfizer thing.

Paul: He said with technologically that is impossible and has been determined to not be accurate. He said that the bill doesn't do anything to preserve the patent or the life on their products. He gave an example and said they are always coming up with new products to replace the ones that go generic; it is part of the process.

Senator Schneider: Asked if he could give an example of what the pop ups look like.

Paul: He said that they are similar to what you would experience on your home computers with pop ups. He said they should focus on those for the patients' safety and not the ones that encourage doctors to prescribe another drug.

Senator Larsen: Said that he was talking about the doctors doing a prescription and an alert comes up saying that those two drugs don't work, this bill when it says including alerts, is that the alerts that they want to get rid of?

Paul: No this bill says commercial alerts to track a doctor and switch them to another product. He said it doesn't say you can't give an alert about a drug interaction. He said even if the system comes in with a safety alert a physician can override it.

Ken Tupa, Pfizer: Said that he was asked by Susan Helgeland, Executive Director of Mental Health America of North Dakota to provide her testimony to the committee in support of 1422. Testimony Attached (2).

Pat Ward, Attorney for Medco Health Solutions: Testimony Attached (3). He is testifying in opposition to House Bill 1422.

Chairman Klein: Asked Howard to come up and tell them what the difference was between 2122 and the one they are dealing with today.

Howard C. Anderson, Jr, R.PH, Executive Director of the Board of Pharmacy of North Dakota: He said that prior authorization and 2122 were different things. He said what they are talking about in this bill is a method for prior authorization and Senate 2122 specifies how a physician selects a particular brand or a particular generic, it just specifies how he does that by writing brand medically necessary. He said he could also select the box in the e script standard that says he wants brand medically necessary and there are two steps he has to do.

Mike J. Ayottte, a Pharmacist and Director of Government Affairs for North Dakota for CVS Trademark: Testimony Attached (4). Included with a copy of the Florida statues and printed version of computer page with the e script.

Senator Laffen: Asked for him to describe what this bill will eliminate.

Mike: Said that it takes out the alerts and messages. They would not be able to message or alert the physician for any of these issues. He said it doesn't say commercials, it says alerts and messages. He said he feels this would stop e prescribing and not enhance it.

Senator Laffen: Asked what page which box would go away if they pass the bill.

Mike: He said he didn't think you could tell according to the bill but he doesn't think they could give them the smiley faces, alternatives or message on prior authorization, you wouldn't be able to message any of this based on the bill. He said that if they strike the alerts and the messaging then he would support it.

Senator Nodland: He said so the doctor that doesn't use e prescribing where does he get this information.

Mike: He doesn't, he would have to know it from experience of having had patients. He said this basically does the work for everyone up front.

Chairman Klein: Said aren't there numbers that doctors' spend a lot of time chasing the paper trail and we could help them by doing this?

Mike: Said the issue is this informs the doctor of what the decision means, so the patient and doctor know the impact of what they are doing. If you want to copy Florida you need to do it the way it is written. He said that pop up adds do not exist in the system.

Chairman Klein: He asked if as representing one of the larger pharmacies benefit managers, this is how he envisions this as being the problem; you are representing that side of the industry today are you not?

Mike: Said yes and they also have seventy two hundred pharmacies that use e prescribing all the time. It is a much simpler process. He also said they agree with the language from Minnesota and the language that is being quoted is not the language used. He said the difference in the language is what they oppose.

Senator Nodland: Asked if the doctors who have done this before with the information and knowledge they have, who is putting this software together and giving you the little smiley faces, is that all the information they have received from their studies before or is it the software writer, who is putting that together..

Mike: Said that the software writer has nothing to do with this. When they manage a benefit for someone, there is something called a pharmacy and therapeutic committee; they come up with a formulary for the client based on what they would like to have for their patient population. It is all scientifically based, non-biased individuals. That is then applied to this. If everyone around this table had a different benefit, every formulary would be different because they are not all consistent. It makes it simplistic for physicians because they don't have to worry about each of your individual formularies. It gives them guidance but does not stop them from dispensing what they feel is correct.

John Vastag, Director of Legislative Affairs for Sanford Health and the Executive Director for Health Policy Coalition: Introduced Laura and Gayle who this bill impacts.

Gayle Ziegler, Pharmacist at Sanford Health: Testimony Attached (5).

Laura Davison, RN-Manager, Information Technology: She answered a question about the pop ups and said she doesn't know how a pop up would get into their electronic patient records because it is all secure information. She explained how it worked.

Marlowe Kro, AARP of North Dakota: Testimony Attached (6).

Rob St. Aubyn, Blue Cross Blue Shield of North Dakota: Testimony Attached (7).

Howard C. Anderson, Jr, R.PH: Testimony Attached (8), Neutral Testimony.

Questions

Harvey Hanel, Pharmacy Director at Workforce Safety and Insurance: Neutral Testimony. He said he wanted to make them aware that there are other medication prior authorizations other than what relates to formulary issues. Said this bill does address those

and for the large part but their issues is with medication prior authorizations that are non-formulary and related to issues of liability. He gives an example.

Sheldon Wolf, the North Dakota Health Information Technology Director: Testimony and Proposed Amendment Attached (9).

Dr. Brendan Joyce, Administrator of Pharmacy Services for the Medical Services Division of the Department of Human Services: Testimony Attached (10).

Chairman Klein: Closed the hearing.

2011 SENATE STANDING COMMITTEE MINUTES

Senate Industry, Business and Labor Committee
Roosevelt Park Room, State Capitol

HB 1422
March 23, 2011
Job Number

☐ Conference Committee

Committee Clerk Signature

Explanation or reason for introduction of bill/resolution:

Relating to electronic drug prior authorization standard

Minutes: Discussion and Amendment

Chairman Klein: Said he had some amendments to 1422. This deals with electronic prior authorization. He went over the amendment and the changes it will make. He said it addresses some concerns by Sanford and Medicaid and Medco on what redefines the word group purchaser as the payer, this addresses that language. In addition Senator Laffen gave me some of the Florida language that is also added into here. There were some concerns about the word alerts and we are removing, "alerts", which is consistent to the Florida statute. There was also a concern by the hospitals and they wanted, "commercial messaging" added, so we added the word, "commercial" ahead of the word messaging. They also addressed an issue with Medicaid by removing, "or otherwise". He continues going over the changes, Amendment (1).

Senator Larsen: Asked if the language on page one lines 19-21 were from the Florida statute.

Chairman Klein: Said it was from Vermont. He continues going over the amendment and then calls Representative Weisz to come up and comment on the amendment.

Representative Weisz: Said he looked it over, the suggested amendment that is in front of them. He said he doesn't have a problem with it but doesn't feel some things are necessary because it is already spelled out. He felt the language was already clear but it doesn't hurt anything.

Chairman Klein: Said I am not sure of what the concerns were in the House but there were a variety of concerns here and we were hoping to get it workable.

Representative Weisz: Said that it seems to be an issue over prior auth, not over electronic prescribing of prior auth and that isn't what this is about. It doesn't prohibit in anyway information from pop ups about drug to drug interactions and anything that is supported by scientific evidence. He said the whole point is to keep it clear and this does that.

Chairman Klein: He asked for Representative Weisz to go over the process of prior authorization.

Representative Weisz: He said that currently if a patient is on a formulary and the doctor decides that he wants his patient to be on a specific brand and it could even be a specific generic, he would have to do a written request for prior authorization that this person should get this particular drug even though it isn't on the formulary. That is a written process right now. What this does is take it away and part of the argument is that when you can do it electronically and instantaneously instead of going through the written process, the question is will there be more prior auth being done because it is easier. This will make it easier and that is the whole point. If the prior auth system isn't correct now it should be addressed and changed but all this does is allow them to do it electronically where before they had to go through a written process. The argument is that sometimes they didn't ask for a prior auth where they would of just because it wasn't worth the hassle.

Chairman Klein: Asked if they wanted the change if they could be denied.

Representative Weisz: Said that they wouldn't be denied because they obviously can prescribe what they want to prescribe the issue would be will insurance cover it or Medicaid. I am not an expert on how that would work but there is a potential that they wouldn't get the prior auth and then it becomes the patient's responsibility to pay if indeed the insurer wouldn't cover it. I am not aware that it happens often or if at all. He said that they may find out that changes have to be made on how they determine prior auth but that isn't what this bill is about. If they current process of prior auth isn't proper than there should be a bill and take it a look at it and address the issue down the road. This just saves time and efficiency. There has to be protection because you don't want to influence a physician do either want to go for prior auth, they shouldn't be pushed to go for a name brand drug or they shouldn't be pushed away from a particular drug because it is cheaper.

Senator Larsen: Asked about the alerts and what they were to do.

Representative Weisz: Said that they could be a broad array of things. The original language in the way it can out of his committee said that alerts could not be used to attempt to influence, so the alert as far as the drug to drug interaction was fine but because of the concerns it was taken out completely.

Chairman Klein: Said that was helpful.

Senator Andrist: Moved to adopt Senator Klein's amendment.

Senator Nodland: Seconded the motion.

Chairman Klein: Said that they would hold the motion and closed the meeting.

2011 SENATE STANDING COMMITTEE MINUTES

Senate Industry, Business and Labor Committee
Roosevelt Park Room, State Capitol

HB 1422
March 29, 2011
Job Number 16154

☐ Conference Committee

Committee Clerk Signature Ella Lichtel

Explanation or reason for introduction of bill/resolution:

Relating to electronic drug prior authorization standard

Minutes: Discussion and Vote

Chairman Klein: Said we had the amendments and discussed the amendments. He asked if there was any other discussion on the amendment.

Senator Laffen: Moved to adopt the amendment.

Senator Murphy: Seconded the motion.

Senator Schneider: Said that they had a late arriving amendment this afternoon that he hasn't had a chance to review. I don't know if we are taking any additional testimony or not.

Chairman Klein: We didn't take any additional this morning. I wasn't going to take any additional but just have you visit with your concerned parties. It sounds like the rest of the committee is ready.

Senator Murphy: Asked if the Chairman knew what the amendment was about.

Senator Schneider: Said that the individual who sent the amendment was in the room.

Chairman Klein: Asked if there was any further discussion. He said they had addressed a lot of the issues and said they have a good bill here. He called for the roll call vote.

Roll Call Vote: Yes-7 No-0

Senator Laffen: Moved for a do pass as amended.

Senator Murphy: Seconded the motion.

Roll Call Vote: Yes-7 No-0

Senator Klein to carry the bill

11.0684.02003
Title.03000

Prepared by the Legislative Council staff for
Senator Klein
March 25, 2011

3-29-11
1 of 2

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1422

Page 1, line 8, remove "and"

Page 1, line 9, replace "submitted by" with "to"

Page 1, line 9, after "provider" insert "with the provider's electronic prescribing software system"

Page 1, line 9, remove "by a group purchaser"

Page 1, line 10, after "electronically" insert an underscored comma

Page 1, line 10, after "transmission" insert ", by the payer, by the insurance company, or by the pharmacy benefit manager responsible for implementing or adjudicating or for implementing and adjudicating the authorization or denial of the prior authorization request"

Page 1, line 14, remove "alerts,"

Page 1, line 14, after the third underscored comma insert "commercial"

Page 1, line 15, remove "or otherwise"

Page 1, line 19, replace "alert" with "electronic communication sent to the prescriber"

Page 1, line 19, after the first underscored comma insert "including"

Page 1, line 19, after the second underscored comma insert "commercial"

Page 1, line 20, after "be" insert "consistent with the product label,"

Page 1, line 20, after "evidence" insert an underscored comma

Page 1, line 21, replace "must be consistent with" with "meet"

Page 1, line 21, replace "regulations" with "requirements"

Page 1, after line 22, insert:

"3. Electronic prescribing software may show information regarding a payer's formulary if the software is not designed to preclude or make more difficult the act of a prescribing practitioner or patient selecting any particular pharmacy or pharmaceutical."

Page 2, line 1, remove "state department of health and the"

Page 2, line 2, remove "work together to"

Page 2, line 3, replace "group purchasers" with "the payers, insurance companies, and pharmacy benefit managers responsible for adjudicating the authorization or denial of the prescription request"

Page 2, line 6, replace "January 1" with "June 30"

Page 2, line 6, remove "state department of health and the"

Page 2, line 8, remove "between providers and group"

Page 2, line 9, remove "purchasers"

Renumber accordingly

2 of 2

Date: 3/29/11
Roll Call Vote # 1

2011 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. HB 1422

Senate Industry, Business and Labor Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken: ☐ Do Pass ☐ Do Not Pass ☐ Amended ☑ Adopt Amendment

☐ Rerefer to Appropriations ☐ Reconsider

Motion Made By Senator Laffen Seconded By Senator Murphy

Senators	Yes	No	Senators	Yes	No
Chairman Jerry Klein	✓		Senator Mac Schneider	✓	
VC George L. Nodland	✓		Senator Philip Murphy	✓	
Senator John Andrist	✓				
Senator Lonnie J. Laffen	✓				
Senator Oley Larsen	✓				

Total (Yes) 7 No 0

Absent 0

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

Senator Klein's amendment

Date: 3/29/11
Roll Call Vote # 2

2011 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. HB 1422

Senate Industry, Business and Labor Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken: ☑ Do Pass ☐ Do Not Pass ☑ Amended ☐ Adopt Amendment

☐ Rerefer to Appropriations ☐ Reconsider

Motion Made By Senator Laffen Seconded By Senator Murphy

Senators	Yes	No	Senators	Yes	No
Chairman Jerry Klein	✓		Senator Mac Schneider	✓	
VC George L. Nodland	✓		Senator Philip Murphy	✓	
Senator John Andrist	✓				
Senator Lonnie J. Laffen	✓				
Senator Oley Larsen	✓				

Total (Yes) 7 No 0

Absent 0

Floor Assignment Senator Klein

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1422, as engrossed: Industry, Business and Labor Committee (Sen. Klein, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (7 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). Engrossed HB 1422 was placed on the Sixth order on the calendar.

Page 1, line 8, remove "and"

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Page 2, line 9, remove "purchasers"

Renumber accordingly

2011 TESTIMONY

HB 1422

#1

House Human Services Committee

Representative Weisz, Chair

HB 1422 - Electronic Prescribing Legislation

Presented by Paul Plofchan

January 31, 2011

Chairman Weisz and members of the Committee, thank you for the opportunity to discuss and present support for state implementation of electronic prescribing legislation. My name is Paul Plofchan and I am Government Relations Director for Pfizer. Pfizer is the world's largest private research organization and pharmaceutical manufacturer. Our mission is to advance the quality and safety of healthcare through the research and development of innovative new medicines and health management services.

I commend this panel for holding this timely hearing and fostering a policy dialogue on such an important issue. E-prescribing systems that are well implemented promise many benefits; if however, e-prescribing is implemented inappropriately, it could have profound adverse consequences. Given that we are dealing with the health and lives of patients, I urge you to proceed with great care.

Widespread adoption of electronic prescribing eRx will help health care professionals provide quality, safe care to their patients. ERx may help reduce medication error caused by illegible handwriting, misinterpreted abbreviations or doses, and miscommunication between practitioners and pharmacists. ERx enables automated decision support including medication lists, prior authorization, formulary coverage, eligibility determination, and clinical decision support.

The Federal government has recognized the benefit that eRx can bring and in response has provided incentive payments through the 2009 federal HITECH Act in order to support its adoption. In addition, State policymakers across the nation have begun developing and implementing goals and standards to promote e-prescribing. In 2010, strong eRx Initiatives had already begun in over 10 states, with Rhode Island and Minnesota implementing the most comprehensive e-prescribing initiatives. And in just the past month, eRx legislation has been introduced in 16 states.

Pfizer supports the passage of HB 1422 that implements standards for e-prescribing and moves North Dakota toward a higher quality and more efficient health care system. This bill encompasses several core principles that align with our mission of improving the quality and efficiency of healthcare for patients in the U.S. and around the world.

At the heart of these core principles are three basic tenets: 1) put the patient first; 2) support the clinical judgment of professionals without undue influence; and 3) ensure the integrity of the information used in clinical decision-making.

"Putting the patient first" in electronic prescribing means that standards should be created to ensure patient access to appropriate care under the guidance of a skilled professional who is free to interpret and apply clinical evidence to an individual patient's situation.

Appropriately designed, e-prescribing tools can strengthen the vital relationship between a patient and doctor by reducing the time required for administrative work and information management; properly integrated, the information available to them will be far richer than it is today.

Alternatively, information technology can compromise – even irreparably harm – the quality of the physician-patient relationship. The greatest threat is that third parties may use e-prescribing to infiltrate and inappropriately influence the clinical decision-making process at the critical point-of-care. These intrusions, driven by financial interests, represent inappropriate influence and rarely have the patient's best interests at heart.

For example, a doctor may be trying to prescribe an extended release form of a drug for a patient with a cognitive disorder to simplify treatment and improve compliance. A message could pop up:

The four-times-a-day dosing is preferred. Do you want to change?

No.

Are you sure?

Yes.

The QID dose form is 15% cheaper...

...thereby, frustrating the physician by adding unnecessary steps to complete the prescription.

North Dakota has an important role in implementing goals and standards for E-Rx. The federal government has taken the primary steps in tackling such issues. The HITECH

Act requires certification of the vendors used in eRx implementation. But States must take the next step in ensuring that these platforms are implemented appropriately. In framing this issue, I think it is useful to distinguish between the *technology* standards that will make an e-prescribing program possible and the *policy* standards that will establish the ground rules for its use. *Both* sets of standards are essential components of a functional and sustainable e-prescribing infrastructure.

Certification of vendors is a *technology* standards set by the federal government that each state must follow to ensure states are using sound systems. Adoption of this bill in North Dakota will set critical *policy* standards-- such as establishing a zone of autonomy between the physician-patient relationship that is not eroded over time.

In addition to protecting the patient-physician relationship, successful eRx policies that improve quality and efficiency of care *must* ensure that that information relevant to the decision-making process is made available at the point of care.

There currently is no mechanism in Federal or North Dakota's state legislation to ensure that the information presented to aid decision-making is factually correct, reasonably applicable, properly sourced, or subject to consistent and rigorous standards of accountability or balance.

Maintaining information integrity is critical to the development of eRx policies that improve quality and efficiency of care. This bill includes provisions that assure the information presented within the e-prescribing environment is properly sourced and that the parties who put forth information are subject to the same rigorous standards of accountability and balance as required by the FDA for pharmaceutical manufacturers.

House Bill 1422 also provides that an electronic process, with a uniform format, be developed to replace the numerous, highly variable, prior authorization processes currently used by payers as part of drug utilization management programs. This provision not only improves administrative efficiencies and supports the goal of reducing information errors already cited, it also provides real time adjudication of drug authorization, insuring the patient receive the same medicine at the pharmacy they discussed, and agreed to, as part of the office consultation with their physician.

Electronic prior authorization also offers an opportunity to improve QUALITY OF CARE in North Dakota. Prior authorization is, by definition, the selection of criteria to insure that only patients meeting certain criteria receive a medication. As the payers will likely agree, these criteria are established to BOTH insure cost effectiveness and help drive QUALITY in healthcare – insuring other alternatives – including appropriate generic alternatives - are used maximally whenever appropriate. This legislation does nothing to change the criteria the payers have set for the use of medicines; the provisions do

not impede a payer's ability to define the appropriate criteria or redefine prior authorization in a way that would impede its continued use. By addressing the excessive burdens of the paper process with available technology, the provisions may actually strengthen prior authorization as a drug management tool.

In order for the full promise of electronic prescribing to be realized, it must be implemented in a manner that stays true to the three core principles I noted this morning: Put the patient first; Provide decision support, not decision control; Ensure information integrity and balance. We believe that adoption of this legislation will improve patient care by ensuring quality clinical information is both readily accessible and highly efficient for the providers.

Again, Mr. Chairman, thank you for the opportunity to discuss this important legislation with the Committee. I would be happy to answer any questions.

Thank you.

#2

BOARD OF PHARMACY
State of North Dakota

Jack Dalrymple, Governor

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Jamestown
Bonnie J. Thom, R.Ph.
Granville
Gayle D. Ziegler, R.Ph.
Fargo
William J. Grosz, Sc.D., R.Ph.
Wahpeton, Treasurer

House Bill No 1422
House Human Services Committee
Fort Union Room – State Capitol Bldg
2:45 PM – Monday - January 31st, 2011

Chairman Weisz, members of the House Human Services Committee, thank you for the opportunity to discuss House Bill #1422 today. Since I had a schedule conflict and could not actually attend this hearing myself, I have asked Daniel Duletski, our PharmD Student Intern to represent the Board of Pharmacy.

Along with motherhood and apple pie, it is hard to oppose legislation which includes the patient's freedom of choice of their pharmacy, the prescriber's freedom of choice to choose any drug available for the treatment of their patient and prohibition of interference with the prescription, between the prescriber and the pharmacist.

Even a streamlined process, as indicated on page 2, line 19 for allowing the physician to seek approval of exceptions when they believe these exception are in the best interest of their patient, is one we could not oppose.

On page 2, lines 22 through 29 these provisions seem to be good components of any electronic prescribing system.

On page 2, line 30 – I do not know what "individually suppressible by the prescriber" means, and without clarification, would eliminate it.

On page 3, lines 1 and 2 we have Senate Bill #2122 working it's way to you, which provides the required mechanism for the physician to select a "Brand Medically Necessary" through the electronic prescribing systems, and I believe that this subsection c is redundant to our Senate Bill.

On page 3, lines 3, 4 and 5 this is a section which is confusing to me and I believe extraneous and unnecessary.

Certainly, under page 3, line 6 the provisions for an "electronic prior authorization" seem to facilitate the work of the physician and the pharmacist in taking care of their patient. Subsection 1 says that this should be required. Subsection 2 says a universal format, which would certainly be in the interest of practitioners seeing a consistent format for prior authorization.

I would need to do some additional research to determine what the National Council for Prescription Drugs Program(NDPDP) eScript Standard utilizes for a prior authorization requests.
Their process is ongoing with pilot projects in place and we do not want it to be too strict in our legislation so we come up as different than the national standard. I have included a few slides from the NCPDP web site to show the work that is ongoing.

Subsection 3 addresses a feed back to the prescriber and this certainly appears to be in the best interest of the patient for proper care.

Subsection 4 provides for "real-time adjudication of the prior authorization request" which might be a goal, but seems a little progressive at this time. Of course, as a patient we would always like to have information on how to appeal a denial of requested medication. But, I am not sure how the eScripts Standard will accomplish this.

In summary, we do not want to stand in the way of cost saving measures realistically instituted by a particular plan sponsor's insurance company. However, we do want to be sure that any electronic prescribing system we institute reasonably provides for the simple and real-time utilization of the tool, so that tool does not stand in the way of what the prescriber perceives as the best care for their patients. As patients, each of us want to go away from the prescribers office and our pharmacy with the realization that we have obtained the best care and best prescription product, at the most reasonable cost, to take care of the problem we went to our physician to solve.

Daniel Duletski, Pharm D Candidate
Howard C. Anderson, Jr, R.Ph.
Executive Director

NCPDP Electronic Prescribing Standards

January 2011

What is NCPDP?

- An ANSI-accredited standards development organization.
- Provides a forum and marketplace for a diverse membership focused on health care and pharmacy business solutions.
- A member driven organization that has been named in various government legislation and rulings, such as HIPAA and the Medicare Prescription Drug Benefit.
- One of several Standards Development Organizations (SDOs) involved in Healthcare Information Technology and Standardization.
- Focus on pharmacy services, and has the highest member representation from the pharmacy services sector of healthcare.

NCPDP Standards Used in Electronic Prescribing

- Formulary and Benefit Standard
  - Pharmacy benefit payers (including health plans and Pharmacy Benefit Managers) to communicate formulary and benefit information to prescribers via technology vendor systems. Information for the prescriber to consider for the most appropriate drug choice for the patient.
    - Which drugs are considered to be "on formulary," and alternative medications for those drugs not on formulary
    - Limitations that may impact whether the patient's benefit will cover a drug being considered (such as age limits, gender limits, step therapy rules, benefit-specific coverage exclusions, etc.)
    - The cost to the patient for one drug option versus another

Prior Authorization

NCPDP Prior Authorization Workflow to Transactions Task Group worked on the exchange of prior authorization information

- When the pharmacy needs to obtain a prior authorization, they use the NCPDP Telecommunication Standard prior authorization transactions. So that piece of the exchange has been available for awhile, and was considered out of scope since it exists.
- The task group had active participation and evaluation of first AHRQ/CMS prior authorization pilots using current transaction sets named in HIPAA. But the transactions were cumbersome.
- Based on industry input, the task group created an XML-based exchange of prior authorization data between provider and plan. CMS provided dispensation for testing of this new transaction for a HIPAA-named function.
- CMS wants industry to put forward the resources and funding to test the XML transactions.
- Information on the transaction is available at http://www.ncpdp.org/mdy_outreach.asp

#3

Testimony
House Bill 1422
House Human Services Committee
Representative Robin Weisz, Chairman
January 31, 2011

Chairman Weisz and members of the Committee: my name is Carlotta McCleary. I am the Executive Director of ND Federation of Families for Children's Mental Health (NDFFCMH). NDFFCMH is a parent run advocacy organization that focuses on the needs of children and youth with emotional, behavioral and mental disorders and their families, from birth through transition to adulthood.

NDFFCMH supports the creation of electronic prescribing transmission standards. These standards will ensure that electronic prescribing in North Dakota will be a system that is safe for patients. This bill understands the importance of the relationship between the doctor and the patient in making decisions regarding medication.

NDFFCMH further supports Electronic prior authorization process. This should speed up the prior authorization process. This process can be completed while the patient is still in the room with their physician. If changes need to be made as a result of the prior authorization process they can be discussed during the visit instead of through phone calls or at the pharmacy.

NDFFCMH understands that electronic prescribing can actually reduce errors and increase patient safety.Thank you for your time.

Carlotta McCleary, Executive Director
ND Federation of Families for Children's Mental Health
PO Box 3061
Bismarck, ND 58502

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#4

TESTIMONY
House Bill 1422 – House Human Services Committee
Representative Robin Weisz, Chairman
January 31, 2011

Chairman Weisz and members of the House Human Services Committee, my name is Susan Rae Helgeland. I am Executive Director of Mental Health America of ND (MHAND). Our non-profit organization is 59 years old in ND and 102 years old nationally. Our Mission is to promote mental health through advocacy, education, understanding and access to quality care for all individuals.

I am here today to support HB 1422 related to electronic prescription transmission. Electronic prescribing with standardized prior authorization provides a more streamlined process that will benefit patient care. With this technology, physicians are able to review a patient's medication history, check drug interactions and ensure coverage by the health plan, all while sitting in the room with the patient.

Thank you for the opportunity to testify

#5

North Dakota Hospital Association

Vision
The North Dakota Hospital Association will take an active leadership role in major Healthcare issues.

Mission
The North Dakota Hospital Association exists to advance the health status of persons served by the membership.

Testimony on HB 1422
House Human Services Committee
January 31, 2011

Good morning Chairman Weisz and Members of the House Human Services Committee.

I am Jerry Jurena, President of the North Dakota Hospital Association. I am here to testify in opposition of HB 1422.

I have a couple of concerns that I would like to address: first there is no standardized authorization form; each insurance company has their own form. This would create a logistical problem trying to compile with the prior authorization requirements.

Another concern is in 45-15.4-03, Section 3. b. on page two; "All available pharmacies both in and out of network, must be readily disclosed to the authorized prescriber". There is no way that this requirement can be met.

In addition to these two issues I am not sure that any current software at this time can meet these requirements. There will need to be enhancements to the current software available for pharmacies to meet these requirements.

I am in opposition to HB 1422. I ask that you give HB 1422 a do not pass.

Jerry E. Jurena, President
North Dakota Hospital Association

PO Box 7340 Bismarck, ND 58507-7340 Phone 701 224-9732 Fax 701 224-9529

#6

surescripts
The Nation's E-Prescription Network

Surescripts Testimony on North Dakota House Bill No. 1422
Relating to Electronic Prescription Transmission
January 31, 2011

Good afternoon Mr. Chairman and members of the committee. My name is Doug Johnson, and I am vice president of PBM/Payer Customer Relations for Surescripts. Surescripts operates the nation's largest health information network, and we support the most comprehensive infrastructure of healthcare organizations nationwide. Pharmacies, physicians, payers, pharmacy benefit managers, hospitals, health information exchanges, and health technology firms rely on Surescripts to more easily and securely share health information. By providing that information during emergencies and routine care, Surescripts is committed to saving lives, improving efficiency, and reducing the cost of healthcare for all. The vast majority of electronic prescription messages transmitted in the United States today flow through our network, and there currently are 790 prescribers and 153 pharmacies in the state of North Dakota actively using our network to exchange such electronic messages. Members of the committee and their staff can learn more about Surescripts by visiting our web site, which is located at www.surescripts.com.

Given Surescripts' central role in the electronic transmission of prescription-related information nationally, we are keenly interested in the requirements that would be made if House Bill 1422 were passed. I thank the committee for allowing me this time to share our thoughts and concerns.

In general, Surescripts has strong concerns about the requirements made by this bill, and we are opposed to the bill as drafted. This might seem an unusual position to take for an organization that is steeped in automation and is promoting the adoption of health information technology, or HIT, nationwide. Thus, let me state for the record that we agree with many of the intended outcomes of the bill. However, our primary concern is that the bill makes requirements with respect to prescription benefit and prior authorization processes that cannot be met now or in the near future by the HIT industry. This bill would make these functionalities mandatory

components of electronic medical record systems and, because these functionalities are not yet technically feasible, would in fact cause e-prescribing in North Dakota to come to a halt.

If e-prescribing was to cease in North Dakota, the associated strides in improved safety, increased in efficiencies, and reduced costs of the prescription-use process would be lost, which certainly would not be in the interest of patients, physicians, pharmacists, and health plans in the state. Further, there are likely other unintended consequences. For example, members of the committee may be aware that the federal government is currently making tens of thousands of dollars of incentive payments available to physicians who adopt electronic medical record systems. E-prescribing is one of the components that electronic medical record systems must have in order for their users to qualify for these incentives. Were e-prescribing to come to a halt in North Dakota, it would hinder the ability of the state's 790 e-prescribers, who each individually might otherwise be eligible to receive tens of thousands of dollars in incentive payments, to qualify to receive them.

It is important to make clear that Surescripts agrees with physicians, pharmacies, and payers that an electronic prior authorization process would be desirable and beneficial. We and other HIT stakeholders, including the National Council for Prescription Drug Programs or NCPDP, which created the e-prescribing technical standards used nationwide, have made several good-faith efforts to create a standard methodology for electronic prior authorization. For example, in 2006, Surescripts piloted an experimental electronic prior authorization process as part of a grant that we received from the federal Centers for Medicare & Medicaid Services to test e-prescribing standards for use in the Medicare program. That pilot determined that the experimental prior authorization process was not ready for adoption. In 2009, we again engaged in another limited pilot of a similar experimental electronic prior authorization process with a small number of industry stakeholders. The results of that second pilot have not been published, but we can share that a key finding was that there was—and still is—a need for an effective national electronic prior authorization standard to be developed. To this day, there is still no viable electronic prior

authorization standard or methodology—available for use in real time or otherwise—in the United States.

The HIT industry, with support from the federal government, has adopted nationally recognized standards to enable e-prescribing nationwide. Without such national standards, the operation of health information networks such as ours would not be possible. Passage of this bill would potentially contribute to a fifty-state patchwork of inconsistent e-prescribing standards that would compromise the efficiencies and interoperability currently being sought by the federal government. This would not be in the interest of patients and their health care providers in North Dakota or the nation at large. Therefore, we recommend that interested stakeholders in North Dakota become involved in NCPDP and join forces with those who share their desire to create a nationally recognized electronic prior authorization standard. We would be happy to share information about participation in NCPDP with any and all such stakeholders.

Finally, the extensive requirements placed on the prior authorization process itself by this bill do not take into account the intricacies of the process, and would be onerous, unwieldy, and unfeasible to implement for the payers, electronic medical record companies, and HIT networks that would have to do so. Passing this bill would compromise the prior authorization process and severely curtail its role as a tool to promote appropriate drug use. This would result in negative financial and operational effects on both private and public health plans, including Medicaid and other state-sponsored plans.

In summary, although we agree with the bill's goal of implementing an electronic prior authorization process, Surescripts is opposed to the passage of House Bill 1422 because it currently is not possible for the HIT industry to meet the bill's technical requirements.

Thank you Mr. Chairman and members of the committee for the time you have given me to share our concerns about this bill. I would be happy to try to answer any questions you may have.

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#7

CVS CAREMARK TESTIMONY
On H.B. 1422

Good afternoon Chairman Weisz and members of the House Human Services Committee. I am Mike Ayotte, a Pharmacist and the Director of Government Affairs for CVS Caremark Corporation. I am here in support of our clients and pharmacists who experience the value of federally standardized e-prescribing system and in opposition to the unworkable and conflicting e-prescribing standards put forth in H.B. 1422.

CVS Caremark Corporation is one of the nation's largest independent providers of health improvement services, touching the lives of millions of health plan participants. We are the largest employer of licensed pharmacists in the United States, with over 25,000 pharmacists nationwide. In North Dakota we currently operate 6 CVS Pharmacies employing over 150 citizens of North Dakota.

Our pharmacy benefit manager (PBM), Caremark, offers our health plan customers a wide range of health improvement products and services designed to lower the cost and improve the quality of pharmaceutical care delivered to health plan participants. Because of the cost containment and formulary management tools Caremark clients utilize, they are able to offer a high-quality, cost effective outpatient drug benefit for their enrollees. Caremark clients include a broad range of highly sophisticated private and public health plan sponsors, including Blue Cross Blue Shield plans, health insurance plans, employers, governments, third-party administrators and Taft-Hartley plans.

In its basic form e-prescribing is a method of communicating that electronically sends an accurate and understandable prescription directly to a pharmacy from the point of care. It is an important part of improving the quality of a patient's care.

CVS Caremark was an early adopter of e-prescribing having recognized the benefits to payers, providers and patients. Since the late 1990's, when the first major e-prescribing companies were developing their e-prescribing solutions, we have experienced a steady increase in e-prescribed prescriptions. The Institute of Medicine report in1999 crystallized the notion that e-prescribing would reduce

medication errors, calling on all physicians to use e-prescribing by 2010. The Federal government followed, including e-prescribing in its Medicare Modernization Act of 2003. The process however requires Federal standards to provide single and simple processes.

I will address a couple of key items in my testimony, but I want to start by stating that the standardization of e-prescribing, from both a technical and policy perspective, is truly a Federal issue. The passage of this bill would stifle the continue development of e-prescribing in North Dakota and may conflict with the national standards. In 2005 CMS published foundation standards that would apply to all Part D prescriptions. If an organization wants to amend these standards or put forth new or additional standards then they should petition CMS on their issues not attempt to place any state in an isolated position by adopting different and possibly conflicting standards. Many organizations testified in 2004 when the National Committee on Vital and Health Statistics Subcommittee on Standards and Security met and have been working on a consensus basis to inform federal regulators. E-prescribing requires national standardization to assure the harmonization of the process. For example, what if North Dakota adopted a different charge card processing standard? This would not allow for anyone to come to North Dakota to use their card nor could someone from North Dakota use their card in another state. A federal standardization process is in place and should be followed.

First, the requirements in the current bill cannot be supported by the current standard.

Secondly, a state-by-state implementation of e-prescribing requirements is counterproductive to the current national standard process and will add costs and decrease the efficiencies and safety that e-prescribing provides.

Third, this bill attempts to create an e-prior authorization standard within e-prescribing. This bill is not the place for such a standard. Currently, there are no standards for this process but national testing is occurring and the proposed language in Section 9 of the bill should be presented to CMS and NCPDP for consideration. NCPDP is the National Council for Prescription Drug Programs and they are the pharmacy industry standards development organization. CVS Caremark did participate in a PILOT study on e-prior

authorization that was built upon our previous work with CMS in demonstration projects. The PILOT was LIMITED in scope and was used to extend our understanding of physician acceptance of e-Prior Authorization. One of the most important outcomes that the e-Prior Authorization pilot demonstrated was that without broad availability of standardized e-Prior Authorization, it is difficult to get prescribers to use the tool. Therefore, the key take away is it is imperative that the industry create a single standard that can be supported and rolled out universally in order to get prescriber adoption. Without a SINGLE standard, the e-prescribing tools cannot be built to support the functionality.

Finally, the bill does address the need for North Dakota to synchronize their current e-prescribing rules with the most recent regulations concerning the e-prescribing of controlled substances by the Drug Enforcement Agency. However, I am not sure a piece of legislation is needed to accomplish that.

This bill attempts to circumvent the national standard setting process. **We ask that you vote against HB 1422 as it will hurt the advancement of e-prescribing in North Dakota and add costs to the healthcare system.**

#8

TESTIMONY BEFORE HUMAN SERVICES COMMITTEE
HOUSE BILL 1422
JANUARY 31, 2011

Mr. Chairman, members of the committee, I am Sheldon Wolf, the ND Health Information Technology Director. I am here today to provide comments on House Bill 1422.

I am not here to argue the merits of prior authorizations and formularies; I will leave that to the providers, insurance companies and drug manufacturers. However, I am here to voice my concern about developing state-by-state system standards that may create inconsistencies and hinder the interoperability of health care records across state lines.

Currently, the Office of the National Coordinator (ONC) and the Center for Medicare and Medicaid Services (CMS) are leading the initiative to develop rules, regulations and standards to increase the interoperability of medical records. These are being developed on a national level to allow records to be interchanged quickly and easily between healthcare stakeholders within and across state borders. The overall goal is to increase the quality of care provided to patients, and hopefully, bend the cost curve.

CMS has realized that standards, rules and regulations are not a quick process and are developing them in stages. Currently, only stage one of three has been developed and they are working on stage two. For stage one, the standards for an electronic medical record system include e-prescribing standards developed by the National Council for the Prescription Drug Program (NCPDP). Additionally, ONC has established a process to certify electronic medical record (EMR) systems using certifying bodies. Certified EMRs provide an assurance to providers that electronic medical record systems they

urchase meet the standards and requirements developed by CMS and the ONC. State specific standards would not be included in this process.

The risk of states developing standards and requirements individually rather than nationally is that 50 different standards may be developed and hinder the interoperability of health care data across state lines. A current example of this is Minnesota's consent rules. Their rule is more restrictive than states around it and, as such, does not allow a quick, easy way to electronically process patient consent to release medical information. To resolve this issue, states in the upper Midwest are working together on a resolution and to develop an electronic process allowing for the interstate interoperability of health records. If a process cannot be developed, handling of consents across state lines could end up staying paper based.

he next concern relates to the requirements in section 43-15.4.04. This section requires that an electronic prior authorization process for allowing approval of an exception to the plan formulary must be required as part of all electronic medical records systems that facilitate electronic submission of prescriptions. Based upon discussion with several providers around the state, electronic prior authorization capabilities currently do not exist in their electronic medical record systems and are not offered, as there is not existing national standard.

While, I agree that this requirement will allow for quicker approval of prior authorizations and ultimately speed up the process, it will also require providers to develop and write this application (vendor or in-house developed) into their current software or forgo purchasing the electronic prescription piece of an electronic medical record. If the second option is selected, providers will continue to do all prescribing and prior authorizations using paper or faxes machines. Additionally, if a provider chooses to

se paper, the provider will not meet the Medicare and Medicaid meaningful use requirement, which requires that providers must electronically prescribe at least 40% of all permissible scripts, and thus may make them ineligible for incentive payments. This leaves a provider in an awkward position, they could:

- modify the EMR, at a time when they are just trying to implement an EMR, usually with a very tight fiscal budget,
- forgo the Medicare and Medicaid incentives and possibly risk receiving a decreased Medicare payment in the future, or
- use the electronic prescribing capabilities without the required prior authorization component and be in non-compliance with this regulation

Additionally, item two requires a universal format to be used for prior authorization requests. To my knowledge, a universal format currently does not exist and the proposed legislation does not identify who will develop this universal format.

As I indicated previously, I do not disagree with the need for standards and the use of electronic prior authorizations. However, I feel that the standards and electronic prior authorization requirement should be developed on a national level to allow for the easy transition of prescriptions and prior authorizations within and across state lines and amongst stakeholders. Additionally, standards and prior authorization requirements developed on a national level will allow electronic medical record vendors to build these processes into their systems for all providers, allowing the development costs to be spread across a lot of providers rather than just North Dakota providers. This take into account changes that payers will need to make to their systems.

Thank you for the opportunity to appear before you today and provide comments on this bill. I would be happy to address any questions.

HB 1422 Amendments

#1

Page, 1, delete lines 13 through 20

Page 2, replace lines 1 through 8 with:

" 2. Electronic prescribing software shall not use any means or permit any other person to use any means, including, but not limited to, alerts, advertising, messaging, and pop-up ads, to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner at the point of care. Such means shall not be triggered or in specific response to the input, selection, or act of a prescribing practitioner or his or her agent in prescribing a certain pharmaceutical or directing a patient to a certain pharmacy. Any alert, advertising, messaging, and pop-up ad must be supported by scientific evidence and must be consistent with the federal food and drug administration regulations for advertising pharmaceutical products."

Page 2, delete lines 13 and 14

Page 2, delete lines 17 and 18

Page 2, delete line 27 through 29

Page 3, delete line 7 through 16 and insert:

The North Dakota board of pharmacy, shall, by July 1, 2012, identify how best to standardize drug prior authorization request transactions, utilizing a universal format for prior authorization, between providers and group purchasers with the goal of maximizing administrative simplification and efficiency in preparation for electronic transmissions and alignment with standards that are or will potentially be used nationally.

August 1, 2013

No later than January 1, 2015, drug prior authorization requests must be accessible and able to be submitted by health care providers, and accepted by group purchasers, electronically through secure electronic transmissions. Facsimile shall not be considered electronic transmission.

States with alerts language in statute

Florida

456.43 Electronic prescribing for medicinal drugs.
(2) Electronic prescribing software shall not use any means or permit any other person to use any means, including, but not limited to, advertising, instant messaging, and pop-up ads, to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner at the point of care. Such means shall not be triggered or in specific response to the input, selection, or act of a prescribing practitioner or his or her agent in prescribing a certain pharmaceutical or directing a patient to a certain pharmacy.
FL. Senate Bill 1408. Enacted; 2006.

Maine

A person may not sell or distribute in the State computer software that influences or attempts to influence a prescribing decision of a prescriber to prescribe a certain drug or that directs a patient to a certain pharmacy. Features of computer software that are prohibited include, but are not limited to, pop-up and other advertisements, instant messages and economic incentives that are triggered by or in specific response to a selection, act or other input or designation of pharmacy by the prescriber or an agent of the prescriber. This subsection does not apply to in-house equipment provided within a hospital for use by prescribers and the hospital pharmacy or to information provided to a prescriber about prescription drug formulary compliance, patient care management or pharmacy reimbursement.
ME. House Bill 1009. Enacted; 2007, c. 362, §2.

New Hampshire

320:2 Prescriptions; Electronic Prescribing. Amend RSA 318:47-c to read as follows:
318:47-c Prescriptions.
(c) Electronic prescribing software shall not use any means or permit any other person to use any means, including, but not limited to, advertising, instant messaging, and pop-up ads, to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner at the point of care. Such means shall not be triggered by or in specific response to the input, selection, or act of a prescribing practitioner or his or her agent in prescribing a certain pharmaceutical or directing a patient to a certain pharmacy.
NH. House Bill 134. Enacted.; 2007.

Vermont

Sec. 21. 9 V.S.A. § 2466a is added to read:
(d) CONSUMER PROTECTIONS; PRESCRIPTION DRUGS (d) No person shall sell, offer for sale, or distribute electronic prescribing software that advertises, uses instant messaging and pop up advertisements, or uses other means to influence or attempt to influence the prescribing decision of a health care professional through economic incentives or otherwise and which is triggered or in specific response to the input, selection, or act of a health care professional or agent in prescribing a specific prescription drug or directing a patient to a certain pharmacy. This subsection shall not apply to information provided to the health care professional about pharmacy reimbursement, prescription drug formulary compliance, and patient care management.
VT. Senate Bill 115. Enacted; 2007.

HB 1422

Pfizer Comments before the North Dakota Senate

Industry, Business and Labor Committee

Senator Jerry Klein, Chairman

Presented by Paul Plofchan

March 9, 2011

Chairman Klein and members of the Committee, thank you for the opportunity to present support for state implementation of electronic prescribing legislation. My name is Paul Plofchan and I am the Government Relations Director for Pfizer in North Dakota. Pfizer is the world's largest private research organization and pharmaceutical manufacturer. Our mission is to advance the quality and safety of healthcare through the research and development of innovative new medicines and health management services.

Widespread adoption of electronic prescribing (eRx) will help health care professionals provide quality, safe care to their patients. ERx may help reduce medication errors caused by illegible handwriting, misinterpreted abbreviations or doses, and miscommunication between practitioners and pharmacists. ERx enables automated decision support including medication lists, prior authorization, formulary coverage, eligibility determination, and clinical decision support.

The Federal government has recognized the benefit that eRx can bring and in response has provided incentive payments through the 2009 federal HITECH Act to support its adoption. In addition, State policymakers across the nation have begun developing and implementing goals and standards to promote e-prescribing. Pfizer has been engaged in the eRx arena at the State and Federal level for some time now, collaborating with many stakeholders, including physician organizations, patient advocacy groups, and pharmacy associations, to promote the implementation of best practice measures in Health Information Technology. Strong eRx Initiatives, independent of Pfizer efforts, have already begun in over 10 states, with Rhode Island and Minnesota implementing the most comprehensive e-prescribing initiatives in 2010. Because Pfizer and other stakeholders are engaged on this at a national level, we are able to inform interested parties and policymakers on best practices and important policy actions occurring across the country. It is from these best practice exchanges that we have become involved with discussions around issues addressed with HB 1422. As a North Dakota employer and health care stakeholder, we have openly and transparently shared ideas

with fellow ND stakeholders, and because of this, Pfizer supports the passage of HB 1422 which implements standards for e-prescribing and moves North Dakota toward a higher quality and more efficient health care system.

This bill encompasses several core principles that align with our mission of improving the quality and efficiency of healthcare for patients in the U.S. and around the world.

At the heart of these core principles are three basic tenets: 1) put the patient first; 2) support the clinical judgment of professionals without undue influence; and 3) ensure the integrity of the information used in clinical decision-making.

"Putting the patient first" in electronic prescribing means that standards should be created to ensure patient access to appropriate care under the guidance of a skilled professional who is free to interpret and apply clinical evidence to an individual patient's situation.

Appropriately designed, e-prescribing tools can strengthen the vital relationship between a patient and doctor by reducing the time required for administrative work and information management; properly integrated, the information available to them will be far richer than it is today.

Alternatively, information technology can compromise – even irreparably harm – the quality of the physician-patient relationship. The greatest threat is that third parties may use e-prescribing to infiltrate and inappropriately influence the clinical decision-making process at the critical point-of-care. These intrusions represent inappropriate influence and rarely have the patient's best interests at heart.

As you know, this bill was introduced into the House Human Service Committee on January 17, 2011 and passed with 91yeas on February 24, 2011. The version of the bill that is presented before you today is the result of the thoughtful approach of multiple Committee and Subcommittee deliberations to ensure that North Dakota implements electronic prescribing in the most appropriate manner. For example, in developing its recommendations on electronic prior authorization standards, the Committee considered input from the National Council for Prescription Drug Programs (NCPDP) to validate the status of current technology and to provide an appropriate timeline for its implementation. With these considerations, the Committee has provided a bill that reflects sound policy recommendations tailored to meeting the specific needs identified during deliberations. Though Pfizer was not a participant in the development of the statutory requirements of HB 1422 which resulted from this process, we respect and support the conclusions of the House Health Committee and fully support the amended measure as it reflects the decisions of North Dakota policymakers on what is right for North Dakota.

The electronic transmission requirement of this bill aims to preserve prescriber practices by preventing interference at the point the prescription is being written, just like there is no direct interference today when a handwritten prescription is made. Current e-prescribing software can lack protections against the use of commercial pop-up messaging designed to promote alternative drugs preferred by the third party payers. These drugs may be preferred not because they are clinically advantageous or even cheaper for the patient, but because of large manufacturer rebates to the third party payer. Uncontrolled, current electronic prescribing process rules allow third parties to insert themselves in the patient room inappropriately and intrusively. 1422 prevents such practices by all stakeholders, including pharmaceutical companies.

The standards for alerts and messaging ensure that licensed prescribers have ultimate control of the prescription, not electronic prescribing vendors, insurers, PBMs, or pharmaceutical companies. Additionally, information sent to enhance patient safety and care, including drug-drug interactions and drug allergy notifications, will improve as 1422 will require all communications to be properly sourced and meet the accountability and fair balance standards promulgated by the FDA for pharmaceutical advertising.

The provision in the bill regarding the appropriate use of alerts and messaging mirrors language already enacted in Florida, Maine, New Hampshire, and Vermont. These states have established eRx language that is widely regarded as "best practice" by national leaders in the eRx space. In 2010, Surescripts acknowledged Florida's effort to advance these technologies with a SafeRx Award for exceptional commitment to advancing quality patient care through e-prescribing. As other states, such as North Dakota, work to enact policies to advance the use of Health Information Technology, these states offer a sound policy framework with which to begin.

The concern was raised in the House Committee hearing that an electronic Prior Authorization requirement may not be feasible due to a lack of available technology. In order to provide clarification on the current status of electronic prior authorization, the House Committee sought guidance from experts in the field. Included in this review was a conference call with the Chairman of the NCPDP Electronic Prior Authorization Task Force, which confirmed for the committee that technology standards for prior authorization have been ready for use and verification since 2009. The Chairman also encouraged state action, along with pilot studies, to validate the technology, and to promote the implementation of the technology.

The current version of the bill gradually implements electronic prior authorization. First the bill would require the department of health and health information technology advisory committee to provide a report to the legislative management that outlines how to best standardize prior authorization in North Dakota. This provides North Dakota with

the flexibility to implement a standard prior authorization process that will then be employed in an electronic system. This approach mirrors similar legislation in Minnesota, where the legislature has already passes electronic prior authorization requirements. As a border state, where some of North Dakota's health services organizations already do business, the MN requirements run in close parallel – the efforts being made to comply with MN law will be transferable to the requirements of 1422.

Electronic prior authorization also offers an opportunity to improve QUALITY OF CARE. Prior authorization is, by definition, the selection of criteria to ensure only patients meeting certain criteria receive a medication. These criteria are established by payers to insure cost effectiveness and QUALITY – ensuring other alternatives – including appropriate generic alternatives - are used maximally whenever appropriate. This legislation does nothing to change the criteria the payers have set for the use of medicines. 1422 automates the process so the physician and patient receive an answer from the payer concerning coverage while the patient is still with their doctor. This allows the physician to discuss the approved medicine with the patient during the office visit or, in the case of denial, to select an alternative, again while the patient is present so appropriate instructions and risk vs. benefits information for the alternative is shared as part of the physician-patient consultation. There is little doubt that such a improvement will drive Quality without detracting from cost effectiveness – after all, the payer criteria is maintained and the payer can say "no" just as fast as they can say "yes".

In order for the full promise of electronic prescribing to be realized, it must be implemented in a manner that stays true to the three core principles I noted this morning: Put the patient first; Provide decision support, not decision control; Ensure information integrity and balance. We believe that adoption of this legislation will improve patient care by ensuring quality clinical information is both readily accessible and highly efficient for the providers.

Again, Mr. Chairman, thank you for the opportunity to discuss this important legislation with the Committee. I would be happy to answer any questions.

Thank you.

TESTIMONY
House Bill 1422 – Senate Industry, Business and Labor
Senator, Jerry Klein, Chairman
March 9, 2011

Chairman Klein and members of the Industry, Business and Labor Committee, my name is Susan Rae Helgeland. I am Executive Director of Mental Health America of ND (MHAND). Our non-profit organization is 59 years old in ND and 102 years old nationally. Our Mission is to promote mental health through advocacy, education, understanding and access to quality care for all individuals.

I am here today to support HB 1422 related to electronic prescription transmission. Electronic prescribing with standardized prior authorization provides a more streamlined process that will benefit patient care. With this technology, physicians are able to review a patient's medication history, check drug interactions and ensure coverage by the health plan, all while sitting in the room with the patient.

Thank you for the opportunity to testify

TESTIMONY IN OPPOSITION TO ENGROSSED HB 1422
SENATE IBL COMMITTEE
Wednesday, March 9, 2011, 9:00 a.m.

Good Morning Chair Klein and Members of the Senate IBL Committee.

My name is Patrick Ward. I am an attorney with Zuger Kirmis & Smith. I represent Medco Health Solutions, a pharmacy benefits manager, in strong opposition to Engrossed HB 1422. Medco covers approximately 111,000 lives in North Dakota or about 17% of the population. In 2009, Medco adjudicated 1.4 million retail scripts in the state. We strongly support electronic prescribing such as would be permitted by SB 2122 which was already adopted by this body. Exhibit 1.

In addition to Medco, some of my other clients have expressed concerns about this bill. State Farm asks what the phrase "group purchaser" means or who it is aimed to cover (used in line 9 on section 1 of the engrossed bill). We understand that several other groups including Sanford Health, the North Dakota Medical Association, the National Community Pharmacy Association, the Department of Human Services, AHIP, Sure Scripts, AARP, North Dakota hospitals, WSI, and others who may not appear at this hearing have very serious concerns about HB 1422. Pfizer has introduced this bill in at least 11 states. These states include Indiana, Kansas, Mississippi, Missouri, Nebraska, New Mexico, New Jersey, North Dakota, Oklahoma, Pennsylvania, and South Dakota.

This bill will not enable electronic prescribing. In fact, e-prescribing is available currently in all 50 states and the District of Columbia. 790 doctors and 153 pharmacies are already electronically connected in North Dakota. Section 1

of the bill will merely confuse the issue and actually hamper electronic prescriptions. Paragraph 2 of section 1 is incongruent and illogical.

Section 1 of HB 1422 is designed to interfere with the operation of existing pharmacy networks like the one in your PERS plan, which use generic drugs, step therapy, and direct mail service and other speciality advice and formulary options to keep plan costs down. Providing your doctor with all available choices at the decision phase, by allowing multiple drug therapy options and important patient health information, leads to better care. I ask you, how would it benefit consumers or patients, if the doctor does not have the complete available patient and plan information from the health plan regarding its formulary and low cost alternatives, at the time of prescribing?

Plan formularies are carefully constructed based on consultation with independent clinical experts including physicians, nurses, pharmacists and academics. Drug management tools such as prior authorization and step therapy are put in place to insure appropriate clinical use of certain drugs that pose a safety risk, have a high potential for off label or experimental use, are very high in cost, or are prescribed at dosages exceeding the highest FDA approved dose. Offsetting this balance will fundamentally alter the nature of a benefit plan by essentially mandating coverage without regard to safety and cost factors. According to a study conducted by the Federal Trade Commission, "large PBMs and small or insured own PBMs have used step therapy and prior authorization programs to lower prescription drug costs and increase formulary compliance."

Exhibit 2 is a list of blockbuster drugs soon to go generic and their 2010 U.S. sales. Exhibit 3 shows your PERS programs potential savings from a generic Lipitor based on 2010 drug spend for Lipitor, which is enormous. If this bill had a fiscal note, it would be in the millions. Exhibit 4 is a New York Times article about the real reason that Pfizer and other brand name drug manufacturers are concerned about several major drugs going generic and why this bill is here.

Exhibit 5 is the current Minnesota statute from which part of section 2 of Engrossed HB 1422 was taken, although the effective date was moved up two years by the House committee. You should kill this bill. However, if you prefer a compromise instead of killing this bill, delete section 1 entirely and revise section 2 to be the same as Minnesota. We could support that. Exhibit 6 describes an ERx incentive program from CMS.

Call me a skeptic, but I believe HB 1422 was introduced by Pfizer in an attempt to prohibit generic prescribing in the future as several of its brand named blockbuster drugs, including Lipitor, Viagra, and others go off patent in the next several years, not out of humanitarian concerns for e-prescribing.

Simply put, this legislation is not necessary to enable an electronic prescribing in North Dakota or anywhere else. In fact, piecemeal legislating in this area by states would more likely slow the process, resulting in a patchwork of different laws around the country inhibiting electronic prescribing.

A great deal of work has already been done on this, at the federal level, using deliberative due process, and advice from many of the stake holders

including the brand name drug manufacturers through the National Council for Prescription Drug Programs or NCPDP. NCPDP is devising an electronic prescribing system to work with Medicare and Medicaid, but which would also be applicable and useful in all 50 states and the District of Columbia. Modern electronic prescribing does not know state geographical borders.

We urge a Do Not Pass on HB 1422.

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Sixty-second
Legislative Assembly
of North Dakota

FIRST ENGROSSMENT

ENGROSSED SENATE BILL NO. 2122

Introduced by

Human Services Committee

(At the request of the State Board of Pharmacy)

A BILL for an Act to amend and reenact subsections 3 and 4 of section 19-02.1-14.1 of the North Dakota Century Code, relating to electronic prescriptions.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. AMENDMENT. Subsections 3 and 4 of section 19-02.1-14.1 of the North Dakota Century Code are amended and reenacted as follows:

3. If a practitioner prescribes a drug by its brand name, the pharmacist may exercise professional judgment in the economic interest of the patient by selecting a drug product with the same generic name and demonstrated therapeutical equivalency as the one prescribed for dispensing and sale to the patient unless the practitioner specifically indicates in the practitioner's own handwriting "brand medically necessary" on a written prescription or expressly indicates that an oral prescription is to be dispensed as communicated. If the prescription is created electronically by the prescriber, the required legend must appear on the practitioner's screen. The practitioner must take a specific overt action to include the "brand medically necessary" language with the electronic transmission. The pharmacist shall note the instructions on the file copy of the prescription, or maintain the digital record as transmitted if it is an electronic prescription. A reminder legend must be placed on all prescription forms or appear on the computer screen of the electronic prescribing system. The legend must state "In order to require that a brand name product be dispensed, the practitioner must handwrite the words 'brand medically necessary'.". The legend printed on the prescription form or appearing on the prescriber's computer screen must be in at least six-point uppercase print or font. The pharmacist may not substitute a generic name drug product unless its price to the purchaser is less than the price of the prescribed drug product. In addition, a pharmacist may not substitute

drug products in the following dosage forms: enteric coated tablets, controlled release products, injectable suspensions other than antibiotics, suppositories containing active ingredients for which systemic absorption is necessary for therapeutic activity, and different delivery systems for aerosol and nebulizer drugs. In the event that any drug listed above is, subsequent to January 1, 1982, determined to be therapeutically equivalent, then the previously mentioned substitution ban is automatically removed for that drug. The pharmacist shall inform the person receiving the drug when a prescription for a brand name drug product does not require that the prescribed drug be dispensed and of the person's right to refuse a generic name drug product selected by the pharmacist. The pharmacy file copy of every prescription must include the brand name, if any, or the name of the manufacturer, packer, or distributor of the generic name drug dispensed. A pharmacist who selects and dispenses a therapeutically equivalent generic name drug product shall assume no greater liability for selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its generic name. The practitioner is not liable for the substitution made by a pharmacist.

4. In the case of a prescription for which a maximum allowable cost program for purposes of reimbursement has been established under title XIX of the federal Social Security Act, the following also apply:

   a. If the practitioner has instructed the pharmacist to dispense as written, the words "brand medically necessary" must also be written on the prescription in the practitioner's own handwriting, or appear as part of the electronic prescription as noted in subsection 3. The pharmacist may dispense a therapeutically equivalent generic name drug product if this handwritten or electronic instruction does not appear on the prescription.

   b. If the pharmacist is instructed orally to dispense a brand name drug as prescribed, the pharmacist shall reduce the prescription to writing and shall note the instructions on the file copy of the prescription. ~~The prescription must then be signed by the practitioner and the words "brand necessary" must also be written on the prescription in the practitioner's own handwriting.~~

c. If the practitioner has not instructed the pharmacist to dispense a brand name drug or medicine and the patient specifically requests a brand name drug or medicine, the patient shall pay the difference between the price to the patient of the brand name drug or medicine and the therapeutically equivalent generic name drug or medicine if the price of the brand name drug or medicine is higher.

(2)

Patrick Ward

From: Stacey Fahrner [SFahrner@primetherapeutics.com]
Sent: Thursday, March 03, 2011 10:20 AM
To: Patrick Ward
Cc: Root, David; Jack McDonald; Jessica Mazer; Ayotte, Mike J.; Robert Harms
Subject: RE: Pfizer Bill - Question about FL

I think Mike sent out an fairly extensive list, but their blockbuster is lipitor, which faces generic competition in November:

Patent Expiring in 2011	Condition	Company	2010 U.S. Sales
Lipitor	cholesterol	Pfizer	$5,329,000,000
Zyprexa	antipsychotic	Eli Lily	$2,496,000,000
Levaquin	antibiotics	Johnson & Johnson	$1,312,000,000
Concerta	ADHD/ADD	Johnson & Johnson	$929,000,000
Protonix	antacid	Pfizer	$690,000,000

Cholesterol fighter Lipitor held the title "best-selling drug" for a few years, and has been a major source of income for the world's biggest drug company, Pfizer (PFE). Lipitor (atorvastatin) was released in 1998, and by 2006 it had reached peak sales of $12.9 billion, accounting for 27% of the company's revenue. In 2010, with $10.8 billion in sales, Lipitor still accounted for 15.8% of total revenue, even with the addition of Wyeth's operations.

In 2008, Pfizer reached an agreement with Indian generics manufacturer Ranbaxy Laboratories. Ranbaxy will have a license to sell atorvastatin in the U.S. effective Nov. 30, 2011, and have exclusivity for 180 days before other drugmakers can enter the market. Watson Pharmaceuticals will also introduce a generic for Lipitor.

Between 2010 and 2012, drugs that make up 42% of Pfizer's pharmaceutical revenue will lose patent protection, among them the antacid **Protonix**. The loss of exclusivity on so many drugs -- among them antipsychotic Geodon, with $890 million in U.S. sales in 2010; erectile dysfunction drug Viagra with $1.015 billion; overactive bladder drug Detrol/LA with $693 million; and eye pressure lowering medicine Xalatan with $616 million to name some -- will deeply impact Pfizer.

See full article from DailyFinance: http://srph.it/gEPtSu

Stacey Fahrner
Vp Government Affairs
Prime Therapeutics
tel 202.280.2013

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Population	NDPERS
Dates	1/1/2010 – 12/31/2010

Savings from Generics[1]			
	2010 (baseline)	**+ 1%**	**+ 5%[5]**
Generic Fill Rate	71.7%	72.7%	76.7%
Total Annual Savings	[2]	$370,165	$1,850,826
Member Annual Savings	[3]	$121,052	$605,264
ND PERS Annual Savings	[4]	$249,112	$1,245,562

[1]1% increase in generic fill rate = 1% savings

[2]Total 2010 cost $37,016,525

[3]Total 2010 Member Contribution $12,105,282

[4]Total 2010 Plan Contribution $24,911,243

[5] Prime Therapeutics LLC Analysis of drug claims within the Blue Shield of California system found 5.9% greater generic utilization and 3% better formulary drug use among those whose prescription was submitted electronically. Improved generic and formulary drug use led to an average cost savings of 17.3% for both the member and the payer.

Savings from Generic Lipitor*	
	Total
Lipitor 2010 Spend	$818,413
Avg. Cost Brand Drug[1]	$155.00
Avg. Cost Generic Drug[1]	$40.00
Potential Savings on Lipitor	**$605,626**

* In 2010, NP PERS spent more on Lipitor than any other brand drug except one

[1]National Association of Chain Drug Stores, Industry Facts-at-a-Glance, available at http://nacds.org/wmspage.cfm?parm1=6536#pharmpricing (accessed January 31, 2011).

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Patent Woes Threaten Drug Firms

By DUFF WILSON

At the end of November, Pfizer stands to lose a $10-billion-a-year revenue stream when the patent on its blockbuster cholesterol drug Lipitor expires and cheaper generics begin to cut into the company's huge sales.

The loss poses a daunting challenge for Pfizer, one shared by nearly every major pharmaceutical company. This year alone, because of patent expirations, the drug industry will lose control over more than 10 megamedicines whose combined annual sales have neared $50 billion.

This is a sobering reversal for an industry that just a few years ago was the world's most profitable business sector but is now under pressure to reinvent itself and shed its dependence on blockbuster drugs. And it casts a spotlight on the problems drug companies now face: a drought of big drug breakthroughs and research discoveries; pressure from insurers and the government to hold down prices; regulatory vigilance and government investigations; and thousands of layoffs in research and development.

Morgan Stanley recently downgraded the entire group of multinational pharmaceutical companies based in Europe — AstraZeneca, Bayer, GlaxoSmithKline, Novartis, Novo Nordisk and Roche — in a report titled "An Avalanche of Risk? Downgrading to Cautious." The analysts wrote, "The operating environment for pharma is worsening rapidly."

The same concerns apply to drug giants in the United States. They are all struggling with research failures as they scramble to replace their cash cows, like Pfizer's multimillion-dollar gamble on a replacement for the cholesterol-lowering drug Lipitor, which failed miserably in clinical trials. Drug companies cut 53,000 jobs last year and 61,000 in 2009, far more than most other sectors, according to the outplacement company Challenger, Gray & Christmas.

"This is panic time, this is truly panic time for the industry," said Kenneth I. Kaitin, director of the Center for the Study of Drug Development at Tufts University in Medford, Mass. "I don't think there's a company out there that doesn't realize they don't have enough products in the pipeline or the portfolio, don't have enough revenue to sustain their research and development."

While industrywide research and development spending has nearly doubled to $45 billion a year over the last decade, the Food and Drug Administration has approved fewer and fewer new drugs. Pfizer and Eli Lilly had major setbacks last year in once-promising Alzheimer's drug experiments. Merck stopped testing its top acquisition from its merger with Schering Plough, a blood thinner that caused dangerous amounts of bleeding.

Drug company executives have begun addressing the calls for reinvention.

"We have to fix our innovative core," Pfizer's new president, Ian C. Read, said in an interview recently. To do that, the company is refocusing on smaller niches in cancer, inflammation, neuroscience and branded generics — and slashing as much as 30 percent of its own research and development spending in the next two years as its scientists work on only the most potentially profitable prospects.

Consumers should see a financial benefit as lower-cost generics replace the expensive elite drugs, but may suffer in the long term if companies reduce research and do not produce new drugs that meet the public's needs.

"You don't lay off R&D if it's just a cycle," says Erik Gordon, a clinical assistant professor at the University of Michigan business school who follows the pharmaceutical industry. "That kills progress."

The federal government is also concerned about the slowing pace of new drugs coming from the industry. Francis S. Collins, director of the National Institutes of Health, recently proposed a billion-dollar drug development center at the agency.

"We seem to have a systemic problem here," Dr. Collins said, adding that government research efforts were intended to feed the private sector, not compete with it.

Mr. Read of Pfizer says new products can replace some but not all of the patent losses.

"The hurricane is making landfall," said Jeremy Batstone-Carr, an analyst at Charles Stanley Securities, but he added that Pfizer is among several drug companies giving solace to shareholders by returning money through stock buybacks and dividends. Pfizer's best asset, he said, is its $20 billion stockpile of cash. Yet since 2000, Pfizer's and Merck's share prices dropped about 60 percent, while the Dow rose 19 percent.

Several of the drug titans have bought competitors with newer products to fill their own sales gaps, essentially paying cash for future revenue as their own research was flagging. In the last two years, Pfizer paid $68 billion for Wyeth, Merck paid $41 billion for Schering-Plough, Roche paid $46 billion for Genentech, and Sanofi-Aventis paid $20 billion for Genzyme.

Henry G. Grabowski, a professor of economics and director of the Duke University program in pharmaceutical health economics, likened the recent pharmaceutical megamergers to those that occurred in the banking and telecommunications industries when they were hit by financial shocks in the 1990s.

But he warned that this wave would not guarantee significant research developments in the long term.

"It's never been shown that these big horizontal mergers are good for R&D productivity," Dr. Grabowski said. "I'm in a show-me mode that they get you any real advances other than some short-term cost efficiencies that wear out."

As they move beyond the blockbuster model, companies are refining their approach toward personalized medicines and forming more partnerships. Using genetic or other tests, the plan is to sell new drugs not to millions and millions of people, but to those who would most clearly benefit.

Still, the industry faces intense pressure from generic competition and has tried every tactic to ward it off, including extended-release versions of the same medicine and new pills that combine two ingredients. But 75 percent of all prescriptions in the United States are now low-price, low-profit generic drugs.

At the same time, pharmaceutical companies are being urged by managed care and government health programs to cut prices and improve reimbursement terms for their most profitable pills.

That follows similar practices in Europe, where Germany and the Britain, among other countries, are all increasing pressure for lower drug prices.

"Europe is an ugly place to do business today and will be in five years' time," Christopher A. Viehbacher, chief executive of the French drug giant Sanofi-Aventis, said in an interview.

In the United States, Mr. Viehbacher said generic drugs were taking over the primary care market, leaving the best growth potential in specialty markets and in emerging nations like China, Brazil and Indonesia.

Even in those markets, health systems will not be the profit centers that the United States has been. China, emerging this year as the third-largest pharmaceutical market behind the United States and Japan, plans to cut hundreds of drug prices by an average of 40 percent.

The drug industry has long said that Americans fueled the research engine, spending much more per capita on prescriptions than in any other nation, and paying the highest prices for prescribed medicines.

Drug industry lobbyists have beaten back Democratic proposals to set prices at the lower levels of nations like Canada or to allow Medicare to directly negotiate prices. The industry, by supporting President Obama's health care overhaul, capped its contribution at $90 billion over 10 years in return for the promise of up to 32 million newly insured customers starting in 2014.

The new law also contains a major threat to drug industry profits in a little-known section that would allow centralized price-setting. Beginning in 2015, an independent board appointed by the president could lower prices across the board in Medicare unless Congress acted each year to overrule it. Medicare pays more than 20 percent of the nation's retail drug bills.

The industry has also been unsettled by the scores of fraud, bribery and kickback cases involving conduct that federal investigators contend have added billions to the nation's drug bill. The penalties have been stiff, and the settlements steep.

In 2009, Pfizer paid the largest criminal fine in the nation's history as part of a $2.3 billion settlement over marketing drugs for unapproved uses. Some analysts say larger fraud and foreign bribery cases will come. The drug companies are responding with extra-careful sales training and vows to restrain marketing zeal. But the change in corporate culture could cost them: internal documents show some of the companies have profited spectacularly from seeking federal approval of a new drug for a limited use, then marketing it far more widely off label.

Other changes are afoot that will no doubt affect the bottom line. They include growing restrictions on gifts, fees and trips to influence doctors to use their products; curbs on the ghost writing of medical journal articles and a push for more disclosure of negative study results. As the golden age of blockbuster drugs fades, so are some of the marketing excesses of the past two decades — the tactics that helped bring in immense profits.

Some analysts see the industry's decline as an investment opportunity. They say drug stocks are good buys because of low price-to-earnings ratios, which typically reflect industry decline or investor pessimism, and high dividend yields averaging more than 4 percent a year.

MN Law

Sec. 5. Minnesota Statutes 2009 Supplement, section 62J.497, subdivision 5, is amended to read:

Subd. 5. **Electronic drug prior authorization standardization and transmission.**

(a) The commissioner of health, in consultation with the Minnesota e-Health Advisory Committee and the Minnesota Administrative Uniformity Committee, shall, by February 15, 2010, identify an outline on how best to standardize drug prior authorization request transactions between providers and group purchasers with the goal of maximizing administrative simplification and efficiency in preparation for electronic transmissions.

(b) By January 1, 2014, the Minnesota Administrative Uniformity Committee shall develop the standard companion guide by which providers and group purchasers will exchange standard drug authorization requests using electronic data interchange standards, if available, with the goal of alignment with standards that are or will potentially be used nationally.

(c) No later than January 1, ~~2011~~ 2015, drug prior authorization requests must be accessible and submitted by health care providers, and accepted by group purchasers, electronically through secure electronic transmissions. Facsimile shall not be considered electronic transmission.

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How To Get Started

IT'S NOT TOO LATE TO START.....

It's not too late to start participating in the 2010 Electronic Prescribing Incentive Program (eRx) and potentially qualify to receive a full-year incentive payment. This web site section is designed to lead you step by step through the process of becoming one of the growing number of eligible professionals who are participating in the program. You may also wish to investigate participating in a separate program known as the Physician Quality Reporting System. For information on the Physician Quality Reporting System go to the **"Related Links Inside CMS"** section of this page and click on the link titled **Physician Quality Reporting System**.

Eligible professionals may begin reporting the eRx measure at **any time** throughout the 2010 program year of January 1-December 31, 2010 to be incentive eligible. Click on the **"Eligible Professional"** link on the left to see if you are an eligible professional. **To successfully meet reporting criteria and be considered incentive eligible, individual eligible professionals must report the eRx measure at least 25 times** (for eligible patient encounters) ***and*** the Medicare Part B Physician Fee Schedule (PFS) allowed charges for services in the eRx measure's denominator should be comprised of 10% or more of the eligible professional's total 2010 estimated Medicare Part B PFS allowed charges.

For 2010, eligible professionals who successfully report the eRx measure will become eligible to receive an eRx incentive equal to 2.0% of their total Medicare Part B PFS allowed charges for services performed during the reporting period. Eligible professionals must have adopted a "qualified" eRx system. There are two types of systems:

1) a system for eRx only (stand-alone)
2) an electronic health record (EHR system) with eRx functionality.

Regardless of the type of system used, to be considered "qualified" it must be based on **ALL** of the following capabilities:

- Generating a complete active medication list incorporating electronic data received from applicable pharmacies and pharmacy benefit managers (PBMs) if available.

- Selecting medications, printing prescriptions, electronically transmitting prescriptions, and conducting all alerts.

- Providing information related to lower cost, therapeutically appropriate alternatives (if any). (The availability of an eRx system to receive tiered formulary information, if available, would meet this requirement for 2010)

- Providing information on formulary or tiered formulary medications, patient eligibility, and authorization requirements received electronically from the patient's drug plan, if available.

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If you have not yet participated in the eRx program, you can begin by reporting eRx data for January 1-December 31, 2010 using any of the following three options:

1. **Claims-based reporting** of the eRx measure. Report only one G-code (G8553) for 2010.

2. **Registry-based reporting** using a CMS-selected *registry to submit 2010 data to CMS during the first quarter of 2011.

3. **EHR-based reporting** using a CMS-selected *electronic health record product, submitting 2010 data to CMS during the first quarter of 2011

*Only registries and EHR vendors who have been vetted by CMS for the 2010 Physician Quality Reporting System/eRx and are on the posted list of registries/EHR vendors are eligible to be considered "qualified" for purposes of reporting the 2010 Electronic Prescribing Incentive Program. These registries/EHR vendors are qualified to report e-Prescribing information to CMS, however, their systems have not been checked for e-prescribing functionality as defined in the specifications of the measure. See **Qualified Registries for 2010** Physician Quality Reporting System **and eRx Reporting available** in the **"Download"** section of this page as well as **Qualified Electronic Health Record (EHR) Vendors for 2010 PQRI and Electronic Prescribing Incentive Programs.**

Before you report this measure, you should ask yourself the following questions:

QUESTION 1: Do I have an eRx system/program and am I routinely using it?

QUESTION 2: Is my system capable of performing the functions of a qualified system as defined in List 1?

QUESTION 3: Do I expect my Medicare Part B Physician Fee Schedule (PFS) charges for the codes in the denominator of the measure (as noted in List 2) to make up at least 10 percent of my total Medicare Part B PFS allowed charges for 2010?

If the answer to all three questions is YES, you may be eligible for an incentive payment equal to two percent of your Medicare Part B PFS allowed charges for services furnished during the reporting period and you should report the eRx measure.

If the answer to the first two questions is YES, but the answer to the third question is NO, you may not be eligible for the incentive payment. However, we encourage you to report the measure. In the event that your Medicare Part B PFS charges for the codes in the denominator of the measure (as noted in List 2) do make up at least 10 percent of your total Medicare Part B PFS allowed charges for 2010, you may be eligible for the incentive payment.

If the answer to either of the first two questions is NO, you cannot report this measure unless you obtain and use a qualified eRx system as defined in List 1.

List 1: What is a Qualified eRx System?

A qualified eRx system is one that is capable of ALL of the following:

1. Generates a complete active medication list incorporating electronic data received from applicable pharmacies and pharmacy benefit managers (PBMs), if available.

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2. Selects medications, prints prescriptions, electronically transmits prescriptions, and conducts all alerts (defined below).

3. Provides information related to lower cost, therapeutically appropriate alternatives, if any (the availability of an eRx system to receive tiered formulary information would meet this requirement for 2010).

4. Provides information on formulary or tiered formulary medications, patient eligibility, and authorization requirements received electronically from the patient's drug plan, if available.
The system must employ, for the capabilities listed, the eRx standards adopted by the Secretary of the Department of Health and Human Services (HHS) for Medicare Part D by virtue of the 2003 Medicare Modernization Act (MMA).

List 2: eRx Measure Denominator Codes (Eligible Cases)

Patient visit during the reporting period (Current Procedural Terminology [CPT] or Healthcare Common Procedure Coding System [HCPCS] G-codes):

90801, 90802, 90804, 90805, 90806, 90807, 90808, 90809, 90862, 92002, 92004, 92012, 92014, 96150, 96151, 96152, 99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99315, 99316, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99345, 99347, 99348, 99349, 99350, G0101, G0108, G0109

Step-by-Step Getting Started

Once You Have Decided That You Want to Participate in the eRx Incentive Program for 2010, You Should Take the Following Steps to Report the Measure:

STEP 1: Did you bill one of the CPT or HCPCS G-codes noted in List 2 for the patient you are seeing?

NO: You do not need to report this measure for this patient for this visit.

YES: Proceed to Step 2.

STEP 2: You should report the following G-code (or numerator code) on the claim form that is submitted for the Medicare patient visit.

G8553 - At least one prescription created during the encounter was generated and **transmitted electronically using a qualified eRx system.**

We encourage you to report the G-code listed in Step 2 above on all of your patient visit claims along with one (or more) of the eligible denominator codes noted in List 2 above. An example of reporting the eRx measure on the Form CMS-1500 (Health Insurance Claim Form) with the new G-code for 2010 is available in the **"Download"** section of this page. Click on the link titled **Claims Based Reporting Principles for eRx.**

STEP 3: To be a successful eRx prescriber and be eligible to receive an incentive payment, you must generate and report one or more electronic prescriptions associated with a patient visit; a minimum of 25 unique visits per year. Each visit must be accompanied by the eRx G-code attesting that during the patient visit at least one prescription was electronically prescribed. Electronically generated refills do not count and faxes do not qualify as eRx. New prescriptions not associated with a code in the denominator of the

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measure specification are not accepted as an eligible patient visit and do not count towards the minimum 25 unique eRx events.

STEP 4: Additionally, 10 percent of an eligible professional's Medicare Part B PFS charges must be comprised of the codes in the denominator of the measure to be eligible for an incentive.

There is NO need to register to participate in this incentive program. Simply begin submitting the G-code on your claims appropriately, report the information required by the measure to a qualified registry, or submit the information required by the measure to CMS via a qualified EHR, if you satisfy the above requirements.

Need Assistance

QualityNet Help Desk
- General CMS Physician Quality Reporting System & E-Prescribing Information
- PQRI Portal Password Issues
- PQRI feedback report availability and access

7:00 AM - 7:00 PM CT

Phone: 1-866-288-8912

Email: qnetsupport@sdps.org

FAQ

Visit our Frequently Asked Questions by scrolling to the **"Related Links Inside CMS"** section of this page and click on the **All eRx FAQs** link. There you will be able to enter keywords in the search box to find answers on "How do I get started" or any other area of the program you may have questions about.

The **PQRI and Electronic Prescribing Quick-Reference Support Guide** is also available to print by clicking on the link in the **"Downloads"** section.

To review all of the 2010 PQRI Program Requirements click on the link titled **2010 PFS Final Rule -- CMS-1413-FC** in the **"Related Links Inside CMS"** section. To review further background information about the Electronic Prescribing Incentive program stroll down on that page to the link titled **"CMS -1413-FC- Published November 25, 2009"** in the **"Related Links Outside of CMS"** and go to page 61849.

Education and Outreach

Coming this fall we will be providing web-based training and educational videos as educational outreach efforts to assist you with implementing our program.

Downloads

2010 eRx Incentive Program Fact Sheet: What's New for 2010 eRx Incentive Program [PDF 318KB]

2010 eRx Incentive Program Made Simple Fact Sheet [PDF 410KB]

Claims Based Reporting Principles for eRx [PDF 87KB]

Qualified Registries for 2010 PQRI and eRx Reporting [PDF 296KB]

Qualified Electronic Health Record (EHR) Vendors for 2010 PQRI and Electronic Prescribing Incentive Programs [PDF 79KB]

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CVS CAREMARK TESTIMONY
On H.B. 1422

Good morning Chairman Klein and members of the Senate Industry Business & Labor Committee. I am Mike Ayotte, a Pharmacist and the Director of Government Affairs in North Dakota for CVS Caremark Corporation. I am here in support of our clients and pharmacists who experience the value of federally standardized e-prescribing system and in opposition to the current standards put forth in H.B. 1422. While we are certainly aligned with the House Committee's intent to increase e-prescribing in North Dakota we believe this bill will not accomplish that goal.

CVS Caremark Corporation is one of the nation's largest independent providers of health improvement services, touching the lives of millions of health plan participants. We are the largest employer of licensed pharmacists in the United States, with over 25,000 pharmacists

nationwide. In North Dakota we currently operate 6 CVS Pharmacies employing over 150 citizens of North Dakota.

Our pharmacy benefit manager (PBM), Caremark, offers our health plan customers a wide range of health improvement products and services designed to lower the cost and improve the quality of pharmaceutical care delivered to health plan participants. Because of the cost containment and formulary management tools Caremark clients utilize, they are able to offer a high-quality, cost effective outpatient drug benefit for their enrollees. Caremark clients include a broad range of highly sophisticated private and public health plan sponsors, including Blue Cross Blue Shield plans, health insurance plans, employers, governments, third-party administrators and Taft-Hartley plans.

In its basic form e-prescribing is a method of communicating that electronically sends an accurate and understandable prescription directly to a pharmacy from the point of care. It is an important part of improving the quality of a patient's care.

CVS Caremark was an early adopter of e-prescribing having recognized the benefits to payers, providers and patients. Since the late 1990's, when the first major e-prescribing companies were developing their e-prescribing solutions, we have experienced a steady increase in e-prescribed prescriptions. The Institute of Medicine report in 1999 crystallized the notion that e-prescribing would reduce medication errors, calling on all physicians to use e-prescribing by 2010. The Federal government followed, including e-prescribing in its Medicare Modernization Act of 2003. The process however requires Federal standards to provide single and simple processes.

I will address a couple of key items from the bill in my testimony, but I want to start by stating that the standardization, from both technological and policy perspective, of e-prescribing is truly a Federal issue. The passage of this bill would stifle the continued development of e-prescribing in North Dakota and may conflict with the national standards. In 2005 CMS published foundation standards that would apply to all Part D prescriptions. If an organization wants to amend these standards or put forth new or additional standards then they should petition CMS on their issues not attempt to place any state in an isolated position by adopting different and possibly conflicting standards. Many organizations testified in 2004 when the National Committee on Vital and Health Statistics Subcommittee on Standards and Security met and have been working on a consensus basis to inform federal regulators. E-prescribing requires national standardization to assure the

harmonization of the process. For example, what if North Dakota adopted a different charge card processing standard? This would not allow for anyone to come to North Dakota from Minnesota or any other state to use their card nor could someone from North Dakota use their card in another state. A federal standardization process is in place and should be followed.

The last industry analysis completed in 2009 showed North Dakota in last place nationally for e-prescribing. In 2009, there were 31 Physicians and 127 Pharmacies utilizing e-prescribing. This was an increase from 2007. However, if you look at prescriptions that were e-prescribed in 2007 there were only 2,612 but in 2009 there 26,844.

I would now like to address the concerns we have with the bill. I need to first of all make it clear there are no pop up ads or advertising on the current

platform. There is no intent to have any– if there were then I believe you would have had e-prescribing USERS requesting this bill.

The first requirement I will address in the current bill is Section 1 Point 2 Lines 13-22 states…"may not use by **any means** or permit any other person to use **any means**, including **alerts**, advertising, **messaging**, and popup advertisements, to influence or attempt to influence through economic incentives or otherwise the prescribing decision of a prescribing practitioner at the point of care. Such means may not be triggered by or be in specific response to the input, selection, or act of a prescribing practitioner or the prescribing practitioner's staff in prescribing a certain pharmaceutical or directing a patient to a certain pharmacy. Any **alert**, advertising, **messaging**, or popup advertisements must be supported by scientific evidence and must be consistent with the

federal food and drug administration regulations for advertising pharmaceutical products." The use of the words "any means" along with alerts and messaging will prevent critical messaging or alerts from reaching the physician at the point of care. This will prevent pro-patient information that will better serve patient's healthcare needs.

I would like to review some of the actual screen shots that will show you the alerts and messaging this bill will prevent and how e-prescribing works today.

SCREEN SHOT HANDOUT

Secondly, I would like to discuss Section 2 of the bill. I understood it to be an attempt to mirror a Minnesota law. This section needs to be revised as it may not currently reflect the Minnesota statue. Below is a link to the law and the actual law section that was attempted to be duplicated.

https://www.revisor.mn.gov/laws/?id=336&doctype=Chapter&year=2010&type=0

Minnesota Session Laws

Key: (1) ~~language to be deleted~~ (2) new language

2010, Regular Session

CHAPTER 336--S.F.No. 2974

An act

relating to health; amending provisions for electronic health record technology; providing for administrative penalties; defining significant disruption to normal operations; appropriating money;amending Minnesota Statutes 2009 Supplement, sections 62J.495, subdivisions 1a, 3, by adding a subdivision; 62J.497, subdivisions 4, 5; proposing coding for new law in Minnesota Statutes, chapter 62J.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2009 Supplement, section 62J.495, subdivision 1a, is amended to read:

Sec. 5. Minnesota Statutes 2009 Supplement, section 62J.497, subdivision 5, is amended to read:

Subd. 5. **Electronic drug prior authorization standardization and transmission.**

(a) The commissioner of health, in consultation with the Minnesota e-Health Advisory Committee and the Minnesota Administrative Uniformity Committee, shall, by February 15, 2010, identify an outline on how best to standardize drug prior authorization request transactions between providers and group purchasers with the goal of maximizing administrative simplification and efficiency in preparation for electronic transmissions.

(b) By January 1, 2014, the Minnesota Administrative Uniformity Committee shall develop the standard companion guide by which providers and group purchasers will exchange standard drug authorization requests using electronic data interchange standards, if available, with the goal of alignment with standards that are or will potentially be used nationally.

(c) No later than January 1, ~~2011~~ 2015, drug prior authorization requests must be accessible and submitted by health care providers, and accepted by group purchasers, electronically through secure electronic transmissions. Facsimile shall not be considered electronic transmission.

I would request amendments to this section to mirror

Minnesota – if that is the Committee's desire.

To conclude, this bill will not drive e-prescribing or e-prior authorization in North Dakota. I have included a recent announcement from the SC Medicaid Department which shows one way states are trying to promote e-prescribing. I would suggest this type of education and outreach will accomplish the desired goal of increasing e-prescribing – however this bill will not. I want to thank you for the opportunity to speak with you today. **We ask that you vote against HB 1422 in its current form as it does not -Lower Patient Costs, Better Patient Health or Deliver Better Patient Care in North Dakota.**

LexisNexis®

1 of 1 DOCUMENT

*** STATUTES AND CONSTITUTION ARE CURRENT THROUGH ACT 2010-283 OF THE 2010A SPECIAL SESSION AND THE NOVEMBER 2010 GENERAL ELECTION ***
*** Annotations current through Dec. 29, 2010 ***

TITLE 32. REGULATION OF PROFESSIONS AND OCCUPATIONS (Chs. 454-493)
CHAPTER 456. HEALTH PROFESSIONS AND OCCUPATIONS: GENERAL PROVISIONS

GO TO FLORIDA STATUTES ARCHIVE DIRECTORY

Fla. Stat. § 456.43 (2010)

§ 456.43. Electronic prescribing for medicinal drugs

(1) Electronic prescribing shall not interfere with a patient's freedom to choose a pharmacy.

(2) Electronic prescribing software shall not use any means or permit any other person to use any means, including, but not limited to, advertising, instant messaging, and pop-up ads, to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner at the point of care. Such means shall not be triggered or in specific response to the input, selection, or act of a prescribing practitioner or his or her agent in prescribing a certain pharmaceutical or directing a patient to a certain pharmacy.

(a) The term "prescribing decision" means a prescribing practitioner's decision to prescribe a certain pharmaceutical.

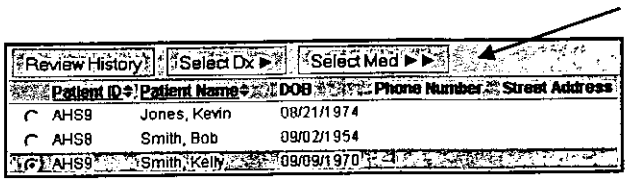
(b) The term "point of care" means the time that a prescribing practitioner or his or her agent is in the act of prescribing a certain pharmaceutical.

(3) Electronic prescribing software may show information regarding a payor's formulary as long as nothing is designed to preclude or make more difficult the act of a prescribing practitioner or patient selecting any particular pharmacy or pharmaceutical.

HISTORY: S. 3, ch. 2006-271, eff. July 1, 2006.

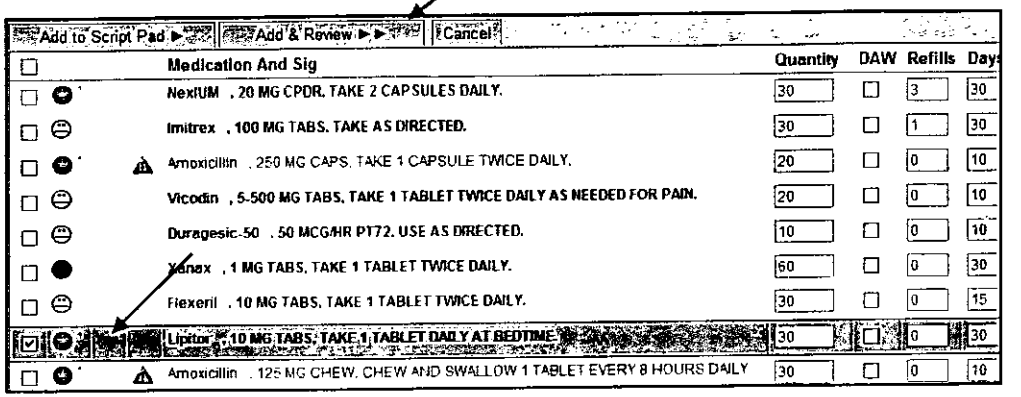
Writing A Script In 4 Easy Steps

1. Select a patient

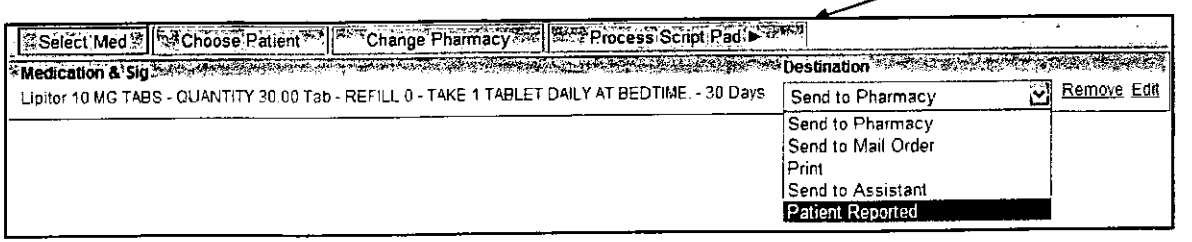


2. Add & Review a medication

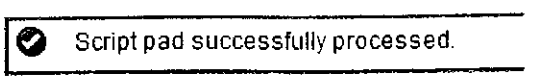
Note: in this application, the provider's "favorites" list shows quick indicators of formulary status using an easy green/yellow/red set of "smiley" faces



3. Process the Script Pad

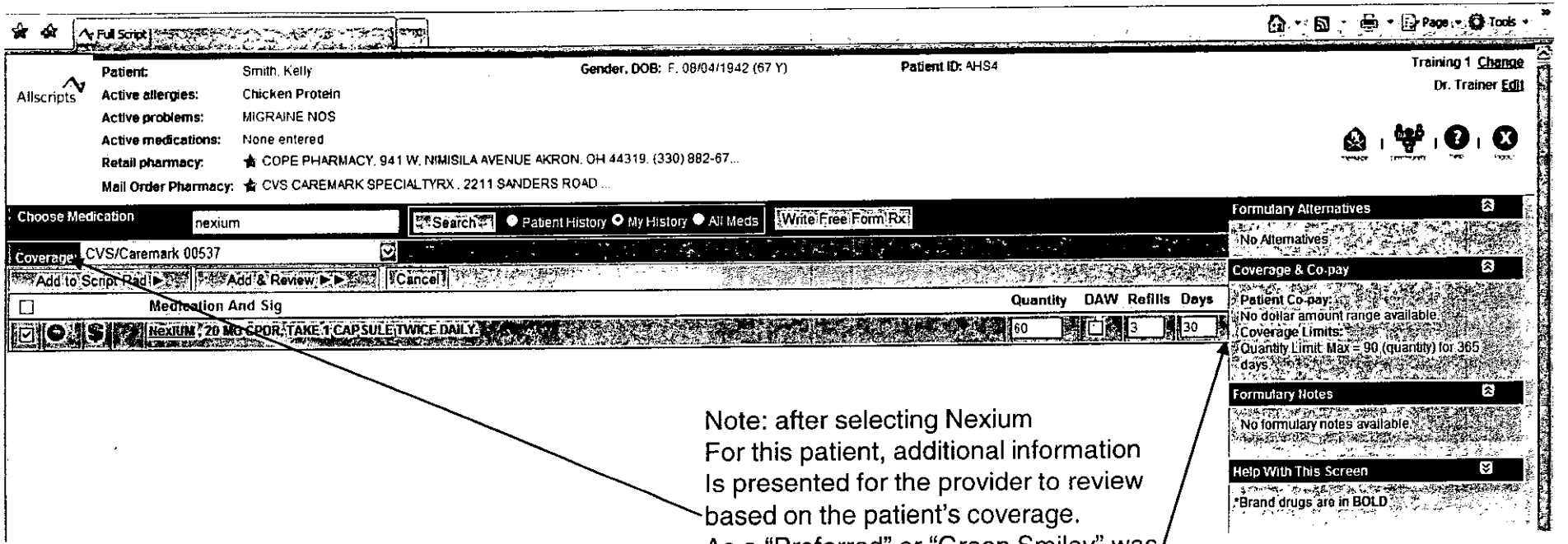


4. Confirm your script has been sent



Choose Medication Screen

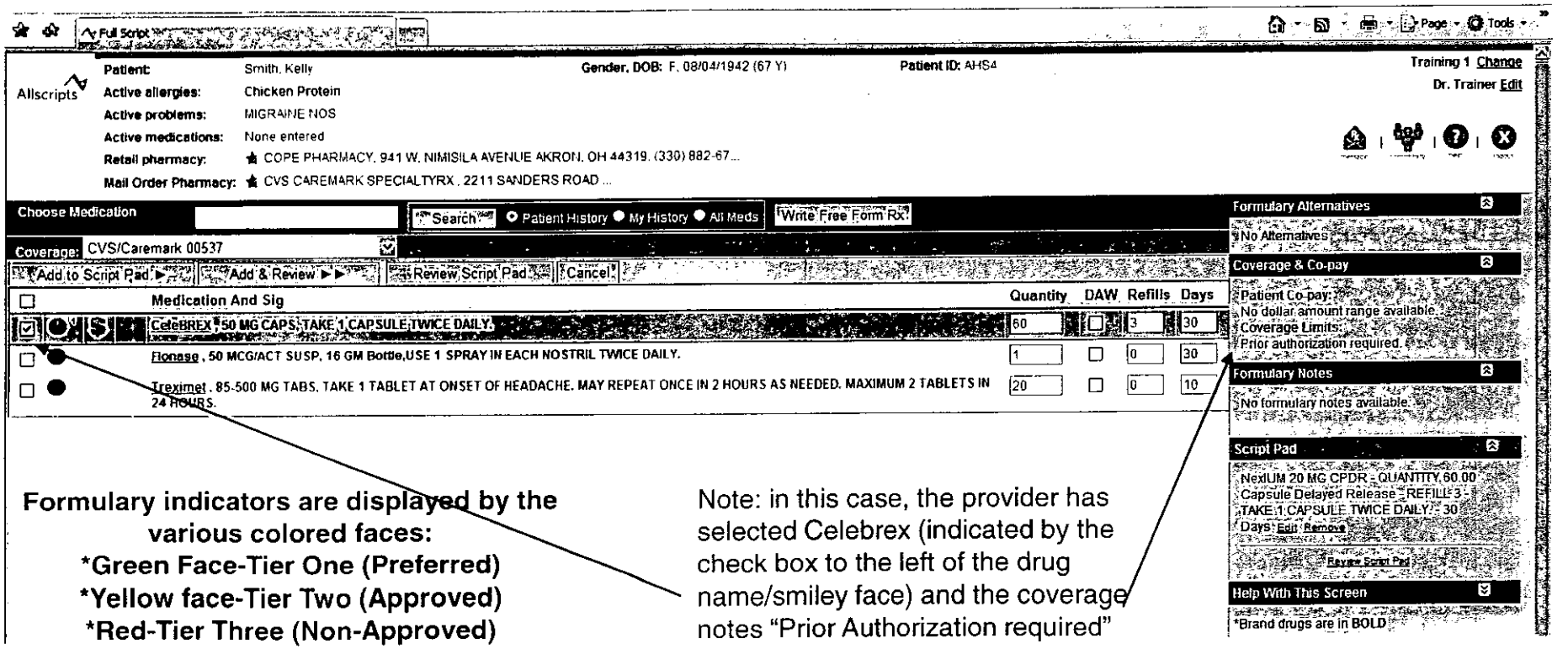
(Select the Medication and Click the Add to Script Pad button)
Note the Coverage & Co-Pay information on the right hand panel



Note: after selecting Nexium
For this patient, additional information
Is presented for the provider to review
based on the patient's coverage.
As a "Preferred" or "Green Smiley" was
Chosen and no additional lower-cost
Alternatives exist on this patient's plan.
There is a Coverage limit and that is
indicated in the Coverage & Co-pay
notes.

Choose Medication Screen

(Select the medication and then click the Add to Script Pad)
Note this prescription needs Prior Authorization under Coverage & Co-pay

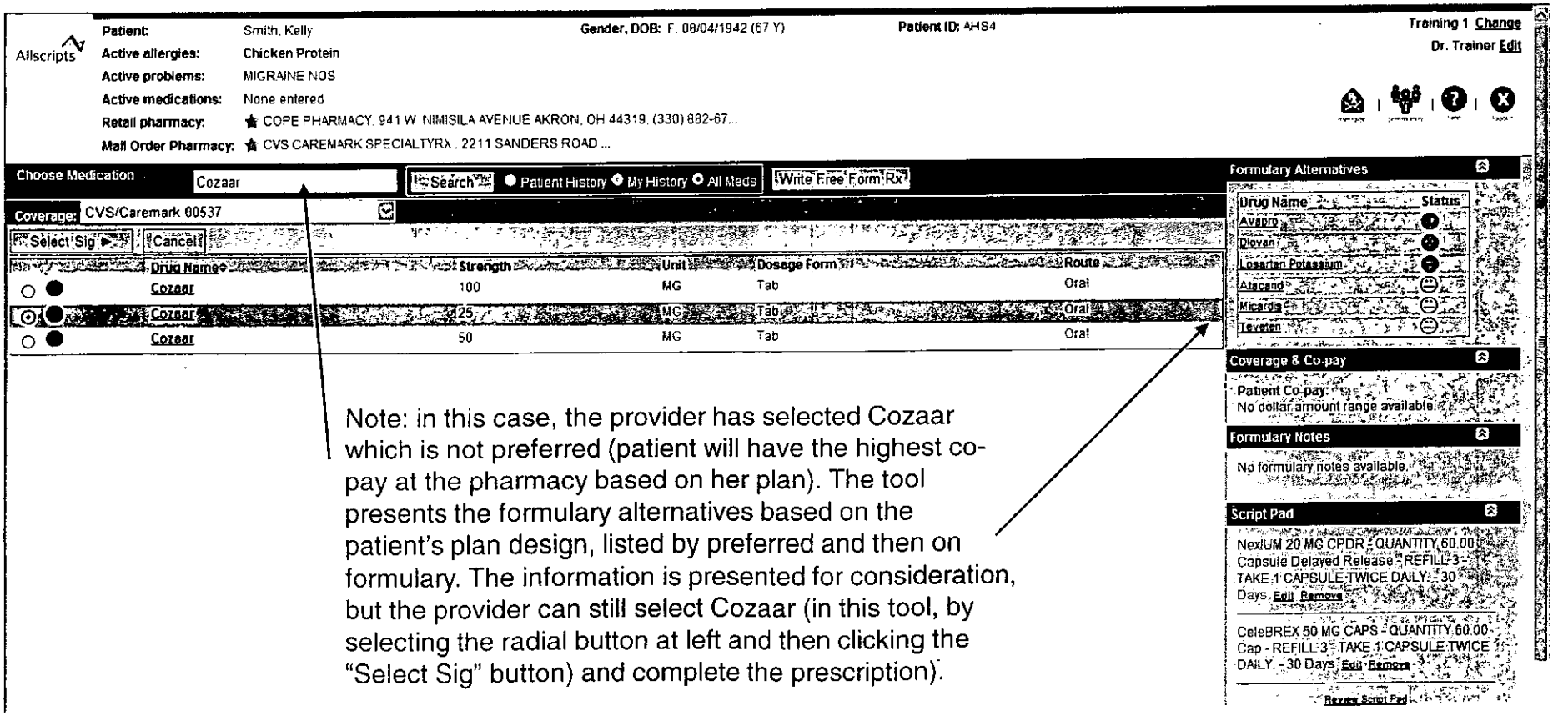


Formulary indicators are displayed by the various colored faces:
***Green Face-Tier One (Preferred)**
***Yellow face-Tier Two (Approved)**
***Red-Tier Three (Non-Approved)**

Note: in this case, the provider has selected Celebrex (indicated by the check box to the left of the drug name/smiley face) and the coverage notes "Prior Authorization required"

Searching for a new medication-Cozaar

(We will click "Select Sig" once we choose the appropriate strength)
Note the Formulary Alternatives in the right hand panel

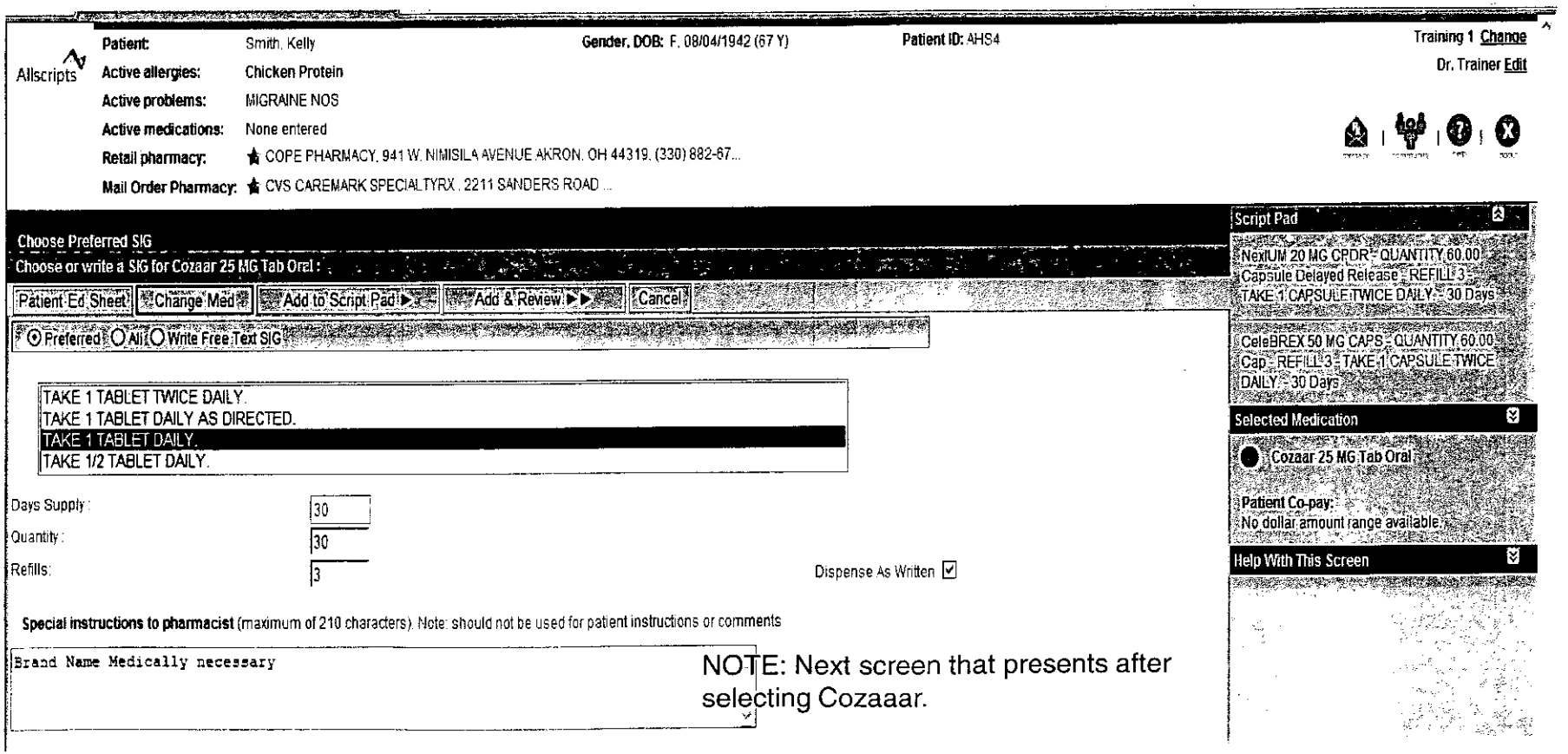


Note: in this case, the provider has selected Cozaar which is not preferred (patient will have the highest co-pay at the pharmacy based on her plan). The tool presents the formulary alternatives based on the patient's plan design, listed by preferred and then on formulary. The information is presented for consideration, but the provider can still select Cozaar (in this tool, by selecting the radial button at left and then clicking the "Select Sig" button) and complete the prescription).

Adding the Sig to the prescription

(We will then click Add & Review to review the script pad)

Note the prior two prescriptions on the script pad in the right hand panel



NOTE: Next screen that presents after selecting Cozaaar.

Ayotte, Mike J.

From: bulletin@scdhhs.gov
Sent: Saturday, March 05, 2011 4:38 AM
To: Ayotte, Mike J.
Subject: Medicaid Rate Reduction
Attachments: MedicaidRatesBulletin20114.pdf

South Carolina Department of
Health & Human Services

Attached is a very important South Carolina Medicaid Bulletin providing updated information regarding the Medicaid program.

If you are having trouble with the attachment use the following link http://www.scdhhs.gov/internet/pdf/MedicaidRatesBulletin20114.pdf

== Medicaid EHR Incentive Program ==

If you're a Physician, Dentist, Nurse Practitioner, Physician's Assistant, or Certified Nurse-Midwife, you may qualify for payments from Medicaid's EHR Incentive Program. To find out more, please visit http://www.scdhhs.gov/hit.

== Technical Assistance for Adopting HIT ==

Also, free assistance is available for most primary care providers with prescription privileges who practice in one of the following specialties (Adolescent Medicine, Family Practice, General Practice, Geriatrics, Gynecology, Internal Medicine, OB-GYN or Pediatrics). To apply for this free assistance in EHR adoption and/or achieving meaningful use, go to http://www.citiasc.org and click on "Apply Online".

If you have questions regarding the content of the bulletin, please contact your Medicaid program manager.

Medicaid Bulletins can also be found at the South Carolina Department of Health and Human Services' web site: www.scdhhs.gov

Thank you.

Comments on House Bill 1422 from Sanford Health, Fargo Region
March 9, 2011

The following document is a formulation of the concerns that Sanford Health, Fargo Region, has regarding House Bill 1422. This summary represents the concerns of the following team which reviewed the bill:

Caryn Hewitt, RN—Chief Clinical Information Officer
Heidi Twedt, MD—Chief Medical Information Officer
Robert Biberdorf, RPh—Vice President Pharmacy
Craig Hewitt—Vice President Information Technology
Susan Schnase, RPh—Director of Retail and Network Pharmacy
Gayle Ziegler, RPh—Pharmacy Supervisor
Melissa Braseth, PT—Manager, Information Technology
Laura Davison, RN—Manager, Information Technology

We have the following concerns regarding the bill:

1) We need clarification of the definition of the term group purchaser.

2) We do not support any type of advertisement in an electronic medical record. We feel we must be allowed to use evidence based clinical decision support and clinical alerts (such as drug-drug interaction checking) at the provider's decision making point. This is in the best interest of the patient/consumer both from a quality perspective, and from a cost perspective.

3) We support the idea of studying the standardization of the prior authorization process. We suggest the team look to the federal government or other states that are also standardizing this process (especially neighboring states) so that the process can be the same in different states. Patients frequently cross state lines to receive care, or have insurance products from another state, so standardization is necessary to the successful implementation of this process.

4) We have concerns about the timeline for implementation of the standardized process being Aug 1, 2013. If the process proposed by the Department of health goes back to the legislature in 2012-2013, we won't know the result of this until spring 2013, and it is unrealistic to think the vendors for the pharmacies, the insurers and the health care providers will all be able to successfully develop the process/product, and the systems will be able to train the user in such a short time frame.

   In one neighboring state, similar legislation was enacted in 2009 that gave the following time frame:

   Basic outline from working group of planned strategy in 2010
   Detailed proposal to be made by January 2014
   If proposal is passed, implementation/enforcement January 2015

   This time frame allowing for years of development and a full year of implementation is much more realistic.

As a result of these concerns, we recommend a do not pass decision on this legislation.

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(66)

Testimony on House Bill 1422
Senate Industry, Business, and Labor Committee
March 9, 2011

Presented by Marlowe Kro
Associate State Director, AARP North Dakota

Chairman Klein, members of the House Industry, Business, and Labor Committee, I am Marlowe Kro, Associate State Director for AARP North Dakota. I am here today on behalf of AARP's 83,000 North Dakota members to speak in opposition to House Bill 1422 relating to electronic drug prior authorization standards.

The goal of electronic prescribing (e-prescribing) is to improve patient safety. Doctors should be able to check for dangerous drug-drug interactions and help patients find affordable options. E-prescribing can provide physicians with clinical and cost information on prescription options that allows them to better counsel patients on which medications – including various lower cost alternatives – will be the safest and most affordable choices.

House Bill 1422 undermines e-prescribing progress by:

1. Prohibiting doctors from seeing all lower cost options.
2. Preventing the technology from showing safety information such as drug-drug interactions.
3. Disallowing any choice of lower cost pharmacy options.

Similarly, electronic health records (EHRs) cannot achieve their full potential if providers don't use functions that deliver the most benefit – for example, exchanging information, and entering orders through the computer so that the "decision support" functions and other automated processes are activated. We can't make real progress on electronic health records if parts of that all-essential, real-time information exchange to enhance appropriate prescribing are disabled.

A research article, "Health Information Technology and Physicians' Knowledge of Drug Costs," (Tseng CW, Brook RH, et al., *American Journal of Managed Care*, April 2010) found that "improving physicians' knowledge of drug costs will require more than simply increasing physicians' use of health IT.... However, unless health IT is designed to make the costs of drugs (and other medical services) automatically available at the point of care, physicians and patients will likely continue to be hampered in obtaining healthcare that is appropriate from both a cost and quality perspective." House Bill 1422 works against this broader health policy goal.

Testimony of HB 1422
Senate Industry Business and Labor Committee
March 9, 2011

Chairman Klein and committee members, for the record I am Rod St. Aubyn representing Blue Cross Blue Shield of North Dakota. Our company is opposed to HB 1422. This bill is simply not needed. The Senate previously passed SB 2122 which we supported. The House amended this bill which did make some improvements. However even with these amendments we strongly oppose this bill. I received the following comments from our Director of Pharmacy Management, Tom Christensen. Tom is a registered pharmacist and a lawyer. Tom was unable to attend today's hearing and asked that I relay his testimony.

Tom emphasizes that the State of North Dakota should not enter into the business of setting e-prescribing standards. For the most part, this responsibility lies with the National Council of Prescription Drug Programs (NCPDP). The NCPDP is a non-profit, standards development organization accredited by the American National Standards Institute (ANSI). The NCPDP has over 1,500 members representing virtually every segment of the pharmacy service industry, including drug manufacturers. The NCPDP v5.1 is the named telecommunication standard for pharmacy claims transactions under HIPAA. NCPDP's SCRIPT Standard and Formulary and Benefit Standard are named e-prescribing standards under Medicare Part D.

Notably, the NCPDP Formulary and Benefit Standard provides a standard means for pharmacy benefit payers (including health plans and Pharmacy Benefit Managers) to communicate formulary and benefit information to prescribers via technology vendor systems. It enables the physician to consider the following kinds of information during the prescribing process, so that he/she could make the most appropriate drug choice for the patient:

- Information about which drugs are considered to be "on formulary," and alternative medications for those drugs not on formulary.
- Limitations that may impact whether the patient's benefit will cover a drug being considered (such as age limits, gender limits, step therapy rules, benefit-specific coverage exclusions, etc.).
- The cost to the patient for one drug option versus another.

It appears this kind of information may be prohibited by the proposed North Dakota legislation which is in direct conflict with federal requirements of Medicare Part D.

The NCPDP has not issued a prior authorization standard but has a prior authorization task force within its e-Prescribing and Related Transactions workgroup. Any attempt to develop a State standard runs the risk of being out of sync with an eventual national standard. It simply does not make any sense in having potentially 50 different state standards versus one national standard.

The need for standardization cannot be underestimated. The thousands of e-prescribing constituents (prescribers, health plans, technology vendors, pharmacies, PBMs) are dependent on

standardization to be able to communicate with each other. The fact that a prior authorization standard has been some time in the coming is evidence of the importance of getting it right.

I also wanted to update the committee in the House Amendments which have incorporated provisions from Minnesota law.

Apparently the Minnesota Department of Health (MDH) was charged with same prior approval responsibilities in the 2009 MN legislative session. The MDH recommendations were controversial and received the following criticism from the Minnesota Administrative Uniformity Commission:

- **Makes poor use of limited financial resources**: The draft report focuses on requiring payers to build web portals. Such a requirement would be a bad investment because the nation is moving towards national standards that will eventually make web portals unnecessary.

- **Still does not reduce the administrative burden or cost**: Web portals do not use the data in the electronic medical record (EMR), and still require administrative processes and human intervention (rekeying data). Thus, they do not achieve administrative simplification or cost reduction.

- **Lacks standards for other processes associated with this transaction**: Under this law there is no standard for the response, so the provider would have to administer multiple processes to communicate with each and every Pharmacy Benefit Management company (PBM)/health plan. In addition, there is no requirement for standardization in the questions contained in the prior authorization request.

These efforts, including any prohibitions or standardization of drug product selection messaging, are best left to national standard setting organizations such as the National Council of Prescription Drug Programs (NCPDP).

Mr. Chairman and Committee members, we strongly oppose HB 1422 and urge that you give it a Do Not Pass.

BOARD OF PHARMACY
State of North Dakota

Jack Dalrymple, Governor

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House Bill No 1422
Senate Industry, Business and Labor Committee
Roosevelt Room – State Capitol Bldg
9:00 AM – Wednesday - March 9th, 2011

Chairman Klein, members of the Senate Industry, Business and Labor Committee, thank you for the opportunity to offer testimony on House Bill #1422 today.

Most of the suggested changes I made on the House side in this Bill, have been accomplished by the amended version, which you now have before you. The current dates in the Bill will allow you to look at it again, if necessary.

The focus of this Bill is currently on establishing a standard prior authorization request to be used by all of the third-party payers when working with electronic prescribing. I believe this would serve all of the prescribers and pharmacists very well, to have a consistent form utilized across all third-party payers. The Bill does establish some dates in the future as the National Council for Prescription Drug Programs [NCPDP] has some pilot programs underway and the XML language necessary to accommodate this request is pretty well developed, but the future timeframe will allow it to be fleshed out and then they should be ready to go with it.

There is some concern that the third-party payer may not be able to use such alerts as, "a generic might be more cost effective" or "utilization of three times a day dosing may allow a much cheaper alternative than the once a day branded product". On the other hand, it also prohibits a band name company from paying to have their brand name flashed before the prescriber's eyes. It is true that brand name pharmaceutical companies are very good at marketing and communicating their message to the prescribers, and this may gain some advantage over the payers.

I want to make it clear that Senate Bill #2122, already passed by you, dealt with the mechanism that a prescriber uses to request that a particular brand, or even a particular generic not be substituted when they have determined that this particular brand or generic is in the best interest of their patient. This bill #1422 does not deal with that issue in any way, shape or form, as it is currently before you. They are totally separate issues.

In summary, we do not want to stand in the way of cost saving measures realistically instituted by a particular plan sponsor's insurance company. However, we do want to be sure that any electronic prescribing system we institute reasonably provides for the simple and real-time utilization of the tool, so that tool does not stand in the way of what the prescriber perceives as the best care for their patients. As patients, each of us wants to go away from the prescribers office and our pharmacy with the realization that we have obtained the best care and best prescription product, at the most reasonable cost, to take care of the problem we went to our physician to solve.

Howard C. Anderson, Jr, R.Ph.
Executive Director

TESTIMONY BEFORE INDUSTRY BUSINESS AND LABOR
HOUSE BILL 1422
MARCH 9, 2011

Mr. Chairman, members of the committee, I am Sheldon Wolf, the ND Health Information Technology Director. I am here today to provide comments on House Bill 1422.

After reviewing the bill, I would like to propose two amendments. Both related to Section 2 of the bill. The bill includes a time line requiring a report to legislative management regarding the outline on how best to standardize drug prior authorizations request transactions between providers and group purchasers. We would suggest that the date of the report be changed from January 1, 2012 to June 30, 2012.

The second change would be to remove "the state department of health and." The Health Information Technology Advisory Committee (HITAC) is located in the Information Technology Department and not the Department of Health. Additionally, both the Chief Information Officer and the State Health Officer (or designees) are members of the HITAC.

Thank you for the opportunity to appear before you today. I would be happy to address any questions.

PROPOSED AMENDMENTS TO SENATE BILL NO. 1422

Page 2, line 6, replace "January 1" with "June 30"

Page 2, line 6, remove "the state department of health and"

Renumber accordingly

Engrossed House Bill 1422 – Department of Human Services
Senate Industry, Business & Labor Committee
Senator Klein, Chairman
March 9, 2011

Chairman Klein, members of the Senate Industry, Business & Labor committee, I am Dr. Brendan Joyce, Administrator of Pharmacy Services for the Medical Services Division of the Department of Human Services, providing information regarding engrossed House Bill 1422.

As it is currently written, Section 1.1 of engrossed HB 1422 will require group purchasers (we assume this includes Medicaid) to accept electronic drug prior authorization requests. There is no current national standard, and if a state standard is developed and used, Medicaid would have to comply with two different standards once a national standard is developed (as would all providers that serve North Dakota Medicaid patients). Changes to the Medicaid claims payment system would be necessary to comply with this portion of HB 1422, but estimates of costs are not possible without any standard in existence.

I would be happy to answer any questions you may have.