

TESTIMONY BEFORE THE HUMAN SERVICES COMMITTEE
May 30, 2012

Mr. Chairman, members of the Committee, I am Sheldon Wolf, the Health Information Technology (HIT) Director. On behalf of the Health Information Technology Advisory Committee, I appear before you today regarding an outline on how best to standardize drug prior authorization request transactions between providers and payers, insurance companies, and pharmacy benefit managers pursuant to Section 2 of 2011 House Bill No. 1422 (see attached).

Pursuant to the bill, a workgroup was formed which includes legislators, pharmacists, association members, board of pharmacy members, payors, and industry experts. This group has been meeting and discussing the needs for prior authorizations, the number of prior authorizations that are being completed, what has been happening in the industry and a strategy for North Dakota moving forward with electronic drug prior authorizations.

Electronic drug prior authorization is the process of obtaining a health plan's approval of a prescription, before filling by a pharmacist, electronically using a direct connection, network, web portal, or other electronic means rather than by letter or fax. The National Council for Prescription Drug Programs listed the following reasons why health plans implement prior authorizations.

Prior Authorization Utilization

Why do health plans implement Prior Authorization?

- Brand name medicines with generic equivalents
- Expensive medicines e.g. specialty medications
- Medicines with age limits, e.g. Retin-A®. Acne is considered to be a condition of children and young adults.
- Drugs used for cosmetic reasons. For example, Propecia®, which is prescribed to re-grow hair or to prevent hair loss.
- Lifestyle drugs e.g. Viagra® and Cialis®.
- Drugs not usually covered by the insurance company, but said to be medically necessary by the doctor. Many different drugs can be used to treat the same condition.
- Drugs that are usually covered by the insurance company but are being used at a dose higher than "normal"
- Off-label usage

30

As illustrated below, prior authorizations can have a large effect on the cost of care by regulating the use of brand name drugs when generic drugs are available or by requiring the use of therapeutic alternatives before brand name drugs are utilized. Below are the effects of one such program.

Effect of Prior Authorization

Market Share

- Celebrex before prior authorization = 33%
- Celebrex after prior authorization = 2.8%
- Spending \$5,785/month instead of \$68,180
- Therapeutic alternatives: ibuprofen, indomethacin, meloxicam, naproxen

- Nexlum before PA = 12.23%
- Nexlum after PA = 2.72%
- Spending \$5,535/month instead of \$24,887
- Therapeutic alternatives: lansoprazole, lansoprazole delayed-rel ODT, omeprazole, omeprazole-sodium bicarbonate, pantoprazole

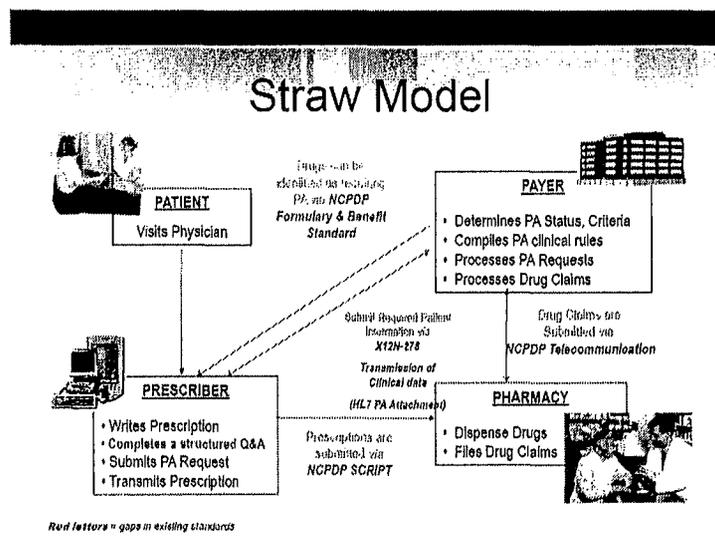
31

For North Dakota, drug prior authorizations average about 120 per month for Blue Cross / Blue Shield and about 256 per month for the Medicaid program.

Workgroup members have indicated that the passage of House Bill No. 1422 and legislative action in other states have helped to move the industry forward on electronic prior authorizations. For example, the NCPDP has restarted work on developing a standard for electronic prior authorizations because of such legislation.

Currently, Humana, Agadia, CVS/Caremark, Surescripts, Cover My Meds, McKesson and Ibeza are conducting industry pilots on electronic prior authorizations. Once these pilots are completed, results will be reported to NCPDP. The information learned from these pilots will be used to develop an industry standard, which will be vetted and ultimately approved as an industry standard. Workgroup members that are part of the NCPDP process anticipate that this will happen later this year.

Below is a straw model on how electronic prior authorizations could work.



For more information about NCPDP, the electronic prior authorization background and their recommendations see the NCPDP letter dated February 29, 2012, which is attached.

We anticipate NCPDP to have a meeting this fall to review the information from the pilot programs, develop and vet the proposed standard and ultimately approve a final NCPDP standard. It is anticipated once the standard is developed it could take a year or more for the payers and providers to implement these standards into their EHR and Payer systems. However, this could take longer because of the time, cost, human resources and other priorities to incorporate into EHR and Payor.

The workgroup has decided to monitor the NCPDP standard setting process to see what standard is approved and when NCPDP will have a final electronic prior authorization standard available, rather than create a state specific standard. The workgroup feels it would be better for all stakeholders to follow a national standard than create a state specific standard.

If the timelines identified after the NCPDP meeting do not allow providers and payers' sufficient time to meet the August 1, 2013 timeline identified in House Bill 1422, a bill to amend that date may be needed and probably would be submitted either by a Legislator or through an agency bill for consideration during the 2013 session.

Thank you for the opportunity to provide you with an outline on how best to standardize drug prior authorization request transactions. I would be happy to answer any questions.

**Sixty-second Legislative Assembly of North Dakota
In Regular Session Commencing Tuesday, January 4, 2011**

HOUSE BILL NO. 1422
(Representatives Weisz, Devlin, Kilichowski)
(Senators Dever, Ugem, Heckaman)

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 to a health care provider with the provider's electronic prescribing software system and must be accepted electronically, through a secure electronic transmission, 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. 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 advertising, commercial messaging, and popup advertisements, to influence or attempt to influence through economic incentives 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 electronic communication sent to the prescriber, including advertising, commercial messaging, or popup advertisements must be consistent with the product label, supported by scientific evidence, and meet the federal food and drug administration requirements for advertising pharmaceutical products.
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.

SECTION 2. ELECTRONIC DRUG PRIOR AUTHORIZATION STANDARDIZATION AND TRANSMISSION - REPORT TO LEGISLATIVE MANAGEMENT. During the 2011-12 interim, the health information technology advisory committee shall establish an outline on how best to standardize drug prior authorization request transactions between providers and the payers, insurance companies, and pharmacy benefit managers responsible for adjudicating the authorization or denial of the prescription request. 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 June 30, 2012, 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.



February 29, 2012

RE: The Electronic Prescribing Adoption Act

Dear Distinguished Entities;

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) -accredited Standards Development Organization consisting of nearly 1,700 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

NCPDP is the organization that has brought together stakeholders in electronic prescribing and electronic prior authorization. Because of industry need, electronic prescribing standards were created in the 1990s. Electronic prescribing is legal in all 50 states, due to industry working with federal and state agencies and Boards of Pharmacy. The industry uses the NCPDP standards for electronic prescribing functions, creating administrative efficiencies and interoperability between healthcare entities, improving patient care.

Outlined below is a brief history of electronic prior authorization and NCPDP's continuing role to develop a standard to implement this process. **It is important to note, that a standard exists in draft form only and awaits appropriate pilot testing prior to finalization.** Currently, several pilot projects are underway by industry stakeholders that are expected to be completed in 2012. It is the intent that a standard will be brought forward based on the findings of these projects and the projects will continue in existence and "go live" at that time.

Electronic Prior Authorization Background

The Health Insurance Portability and Accountability Act (HIPAA) names the ASC X12 278 as the electronic transaction for medication prior authorization to be used by prescribers. In 2006 ePrescribing pilots were sponsored by the Centers for Medicare and Medicaid Services (CMS) and the Agency for Healthcare Research and Quality (AHRQ), pursuant to the Medicare Modernization Act (MMA), to test the use of the electronic prior authorization.

NCPDP convened a multi-Standards Development Organization (SDO) task group of many organizations interested in electronic prior authorization to provide transaction(s) within the requirements of HIPAA. The task group reviewed many prior authorization forms and worked to create the framework for an attachment to exchange prior authorization requirements between prescribers and payers. This was used in the pilot.

A finding of the 2006 MMA ePrescribing pilot was that the ASC X12 278 version 5010 prior authorization transaction (PA) created for service or procedure PA, was insufficient for drug PA. Workarounds were possible but not ideal because developers would be using fields for which they were not originally intended. Participants in the pilot tested a combination of the X12 278, X12 275 and the HL7 PA attachment (modeled after the claims attachment), and found them to be cumbersome and require redundant information. Piloters recommended the multi-standard solution be abandoned for one standard.

In 2008 an expert panel meeting was convened by AHRQ in conjunction with an NCPDP Work Group meeting. The objectives were to update the expert panel on the progress-to-date, including lessons learned of the pilots, and collaborate with expert panel on next steps for electronic prior authorization.

Recommendations by the Panel

- A real-time benefit check transaction be developed.
- The creation of a new XML-based drug electronic prior authorization transaction based on the X12 278 by utilizing the experiences of the NCPDP Prior Authorization Task Group. The new transaction would be compatible with the real-time benefit check.
- Receive approval through the HIPAA Exceptions Process. As spelled out in §162.940 of the Transactions & Code Sets final rule, this involves:
 - Pilot testing under a detailed set of requirements
 - Must be supported by an ANSI-accredited SDO
 - Needs to prove less costly, improve efficiency and effectiveness and not impose additional administrative burden

Status Today

The real-time benefit check transaction has been developed. The XML-based drug electronic prior authorization transaction has been developed and has received approval through the HIPAA Exceptions Process. NCPDP has posted the transaction information at http://www.ncdp.org/industry_outreach.aspx under "Prior Authorization Pilot Information".

In October 2011, NCPDP convened a focus group of interested industry parties. As a result, NCPDP reactivated its Prior Authorization Task Group. In addition, industry pilots were initiated and collaboration through NCPDP continues to date. Humana, Agadia, CVS/Caremark, Surescripts, Cover My Meds, McKesson, and Ibeza are reviewing draft standards, collaborating on enhancements, and then will report status to NCPDP throughout the pilot period. The findings of these projects are expected to be reported to NCPDP for as recommendations for industry approval.

Lastly, NCPDP held an educational Summit that included a report on the current status of electronic prior authorization. This program was held prior to a regularly scheduled NCPDP Work Group meeting in San Diego on February 8th, 2012. A copy of the presentations can be obtained at http://www.ncdp.org/members/EdSummit/6-ANeedforaPriorAuthorizationSolution_2012final.pdf.

Other Concerns of Electronic Prescribing Adoption Act Topics

There are concerns in some of the proposed legislation, which would negatively impact electronic prescribing.

1. Proposed legislation that contains "no intermediary" language would kill or seriously harm the ability to perform electronic prescribing functions. Essential for some entities is the use of intermediaries to handle connectivity requirements that would be costly to build and maintain for organizations, including smaller organizations. This could be interpreted as having a negative impact on the three-way communication workflow among the prescriber, the pharmacy and the nursing facility or nursing centric entity in long-term care electronic prescribing environments.
2. Legislative proposals that include extensive requirements for electronic prior authorization for which there is no proven technical solution at this time. Until the industry pilots are completed and the standard approved by the industry, it is not ready for implementation by the industry, and therefore should not be regulated.
3. Proposed legislation that proposes the development or use of state-level commissions/boards, etc as standards development organizations. This work is already being done at the national level. ANSI-accredited standards development organizations are the organizations that develop the national standards. Organizations, such as NCPDP bring together the stakeholders in the industry to build consensus-based standards.

For more than 30 years NCPDP has been committed to furthering the electronic exchange of information between healthcare stakeholders. NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting, and other functions in the pharmacy services industry as named in HIPAA. The NCPDP SCRIPT Standard, Telecommunication Standard, and the Formulary and Benefit Standard are the standards in use in electronic prescribing as named in MMA, in Meaningful Use, and other federal and state regulations.

For further information from NCPDP, please contact:

Stephen C. Mullenix, RPh
Senior Vice President, Communications and Industry Relations
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260
P: (480) 477-1000 x 127
M: (303) 909-6573
Email: smullenix@ncpdp.org

Lynne Gilbertson
Vice President, Standards Development
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260
P: (480) 477-1000 x 120
Email: lgilbertson@ncpdp.org