2011 SENATE HUMAN SERVICES

SB 2122

2011 SENATE STANDING COMMITTEE MINUTES

Senate Human Services Committee
Red River Room, State Capitol

2122
1-11-2011
Job Number 12762

☐ Conference Committee

Committee Clerk Signature rdmonson

Explanation or reason for introduction of bill/resolution:

Relating to electronic prescriptions.

Minutes: Attachments included.

Senator Judy Lee opened the hearing on SB 2122.

Written testimony was given to the committee as prepared from **Howard Anderson**, Executive Director of the ND Board of Pharmacy, who was unable to be present. Attachment #1

Patrick Ward, Medco Health Solutions, Inc., testified in support of SB 2122 and recommended an amendment. Attachment #2
He pointed out the language in the bill as drafted indicates that if an e-prescription is to be done the practitioner or practitioner's agent must type out "brand necessary" or "brand medically necessary" like they have to do on a hand written prescription. The problem with doing it that way is that it isn't done that way. He explained the format on the computer.

Bruce Levi, ND Medical Association, said the issue as raised by Mr. Ward is consistent with the concerns NDMA has with the legislation. Attachment #3 He felt there was a need to make sure the language is accurate when updating our statutes to acknowledge the practice of e-prescribing.

Dr. Michael Booth, Surgeon in Bismarck, supported the general idea of applying genetic substitution to e-prescribing. He shared the previous concerns about the manner in which this is being proposed. The biggest problem faced when prescribing is getting the message through clearly to the pharmacist. Thought the brand necessary language is unnecessary. He felt it poses an undue burden on the programmers for the e-prescription systems. A simple box to check would be adequate.

Senator Judy Lee talked about the history of brand necessary.

Senator Dick Dever wondered if the pharmacist sees this as a problem.

Dr. Booth said he has had no communication with pharmacists on this specifically. In his experience it is patient driven – they want the brand name and won't stand for anything else.

Implementing the e-prescribing is a slow process.

Robert Harms, CVS, supported the bill and the amendments.

There was no opposing testimony

Dr. Brendan Joyce, Pharmacy Administrator for Medicaid. This is not a Medicaid bill but he was available to answer questions. He said the desire for a checkbox or just a selection is not an option when it comes to the federal law with relationship to Medicaid. He referred to the testimony by Howard Anderson. He talked about the specific field - Note to the Pharmacy - that is not changeable by anyone but the prescriber and once it is sent it is not changeable at all.

Senator Judy Lee asked if it was reasonable to assume that both physicians and pharmacists would prefer not to have two different standards or formats for Medicaid and non-Medicaid prescriptions.

Dr. Joyce responded, yes, it is always easier to have one rule to follow so there is no confusion.

The hearing on SB 2122 was closed.

Senator Judy Lee asked the stakeholders to talk to Howard Anderson and see if they could come up with something that could be proposed. How can it be done so it will satisfy them but not violate what the feds are trying to make us do? Those present agreed to do it.

Discussion followed pertaining to page 2 line 27, using generic unless instructed verbally. It is up to the physicians to specify "brand name necessary". It is not up to the pharmacist to cue the physician to see if they want brand name.

Senator Judy Lee closed discussion until the stakeholders could bring further information back to the committee.

2011 SENATE STANDING COMMITTEE MINUTES

Senate Human Services Committee
Red River Room, State Capitol

SB 2122
2-7-2011
Job Number 14115

☐ Conference Committee

Committee Clerk Signature

Explanation or reason for introduction of bill/resolution:

Minutes: Attachments.

Senator Judy Lee opened SB 2122 for committee work to consider amendments .01001. Attachment # 4. She reminded the committee that there were concerns but the proposed amendments were prepared by legislative council after the concerned parties were in agreement.

Senator Tim Mathern moved to accept the amendments 11.8116.01001.

Seconded by **Senator Dick Dever.**

Roll call vote 5-0-0. **Amendment adodpted.**

Senator Tim Mathern moved a **Do Pass as Amended**.

Seconded by **Senator Gerald Uglem**.

Roll call vote 5-0-0. **Motion carried.**

Carrier is **Senator Spencer Berry**.

11.8116.01001
Title.02000

Prepared by the Legislative Council staff for
Senator J. Lee
January 21, 2011

2-7-11

PROPOSED AMENDMENTS TO SENATE BILL NO. 2122

Page 1, line 10, after ""brand" insert "medically"

Page 1, line 14, after ""brand" insert "medically"

Page 1, line 15, remove "as set forth in this subsection"

Page 1, line 15, remove "For example, the practitioner or the"

Page 1, line 16, remove "practitioner's agent must type out "brand necessary" letter by letter."

Page 1, line 21, remove "or type letter by letter"

Page 1, line 22, after ""brand" insert "medically"

Page 2, line 22, after ""brand" insert "medically"

Renumber accordingly

Date: 2-7-2011

Roll Call Vote # 1

2011 SENATE STANDING COMMITTEE ROLL CALL VOTES

BILL/RESOLUTION NO. 2122

Senate **HUMAN SERVICES** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number .01001

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

☐ Rerefer to Appropriations ☐ Reconsider

Motion Made By **Sen.** Mathern Seconded By **Sen.** Dever

Senators	Yes	No	Senators	Yes	No
Sen. Judy Lee, Chairman	✓		**Sen. Tim Mathern**	✓	
Sen. Gerald Uglem, V. Chair	✓				
Sen. Dick Dever	✓				
Sen. Spencer Berry	✓				

Total (Yes) 5 No 0

Absent 0

Floor Assignment

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

Date: 2-7-2011

Roll Call Vote # 2

2011 SENATE STANDING COMMITTEE ROLL CALL VOTES

BILL/RESOLUTION NO. 2122

Senate **HUMAN SERVICES** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number 11.8116.01001 Title 02000

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

☐ Rerefer to Appropriations ☐ Reconsider

Motion Made By **Sen.** Mathern Seconded By **Sen.** Uglem

Senators	Yes	No	Senators	Yes	No
Sen. Judy Lee, Chairman	✓		**Sen. Tim Mathern**	✓	
Sen. Gerald Uglem, V. Chair	✓				
Sen. Dick Dever	✓				
Sen. Spencer Berry	✓				

Total (Yes) 5 No 0

Absent 0

Floor Assignment Sen. Berry

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

REPORT OF STANDING COMMITTEE

SB 2122: Human Services Committee (Sen. J. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (5 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2122 was placed on the Sixth order on the calendar.

Page 1, line 10, after ""brand" insert "medically"

Page 1, line 14, after ""brand" insert "medically"

Page 1, line 15, remove "as set forth in this subsection"

Page 1, line 15, remove "For example, the practitioner or the"

Page 1, line 16, remove "practitioner's agent must type out "brand necessary" letter by letter."

Page 1, line 21, remove "or type letter by letter"

Page 1, line 22, after "'brand" insert "medically"

Page 2, line 22, after ""brand" insert "medically"

Renumber accordingly

2011 HOUSE HUMAN SERVICES

SB 2122

2011 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

SB 2122
March 15, 2011
Job #15445

☐ Conference Committee

Committee Clerk Signature Vicky Crabtree

Explanation or reason for introduction of bill/resolution:

A bill relating to electronic prescriptions.

Minutes: See Attached Testimony #1

Chairman Weisz: Opened the hearing on SB 2122.

Howard Anderson: Representing the ND State Board of Pharmacy testified in support of the bill. (See testimony #1)

Chairman Weisz: Can you tell me what the DAW = 1 (didn't have his microphone, in audible) or show a brand necessary in there?

Howard: DAW means dispense as written. There are about 8 different codes in the computer that might say dispense as written or might have received it electronically or might receive it by telephone or might have been a written prescription. We even have one that says Indian health service if it came in. Number 8 is HIS. Those tell the pharmacist about the prescription and what its origination was. Number 2 might mean substitution permitted, number 3 might mean it is already a generic.

NO OPPOSITION

Chairman Weisz: Closed the hearing on SB 2122.

2011 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

SB 2122
March 28, 2011
Job #16075

☐ Conference Committee

Committee Clerk Signature Vicky Crabtree

Minutes: You may make reference to "attached testimony."

Chairman Weisz: Take a look at SB 2122. We were sitting on this because of 1422. We will sit on this one and see if they pass it. I'll entertain a motion.

Rep. Devlin: I move a Do Pass.

Rep. Louser: Second.

Rep. Porter: To clarify what this does that we didn't already do.

Chairman Weisz: What we did have more to do with prior auth. The language about maintaining the digital record and some of those issues that aren't address in 1422. Also the part on electronic signature where it says on page 2, line 22, "or appear as part of the electronic prescription as noted in" some of those things they needed for clarification just doing the regular e-prescribing, that is not in 1422. The language in 1213 really is addressed in 1422.

Rep. Paur: As I understand this, if you are going to specify a brand medically necessary like a Bayer aspirin instead of aspirin, currently you have to send a piece of paper that specifies that and you sign that. And they want to do it that electronically. Is that correct?

Chairman Weisz: That is really the prior auth bill that we sent over.

Rep. Paur: No, I think that is with this bill.

Chairman Weisz: Prior auth is what determines the brand.

Rep. Paur: I think one does it pretty much the way I said. Currently if you want to specify a specific brand of medication you can't do it electronically.

Chairman Weisz: This wouldn't allow that either. It says the practitioner must take a specific overt action to include the brand medically necessary language.

Rep. Paur: Yes, another little window would pop up. It is to replace the required paper with a signature that they have now.

Rep. Devlin: My understanding is they just couldn't click a box. If you wanted to use a brand necessary there would be a pop up screen and you had to do something with it to assure that is what you intended. I think Rep. Paur is right. The prior authorization thing was more that they would have to get authorization to use any of the other things. Sort of on a formulary or something.

Chairman Weisz: They can put down the brand medically necessary with the transmission, but they still have to have written authorization to replace a prior auth. This wouldn't affect that. You are right. They can mark it on the prescription that it is medically necessary. So if they already have their written approval on a prior auth, all they have to do is mark this specifically so the pharmacist knows that this is a medically necessary.

Rep. Devlin: I move a Do Pass.

Rep. Louser: Second.

VOTE: 12 y 0 n 1 absent – Rep. Holman

Bill Carrier: Rep. Paur

Date: 3-28-11
Roll Call Vote # 1

2011 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 2122

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. Louser

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

Total (Yes) 12 No 0

Absent 1

Floor Assignment Rep. Paur

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

REPORT OF STANDING COMMITTEE

SB 2122, as engrossed: Human Services Committee (Rep. Weisz, Chairman) recommends **DO PASS** (12 YEAS, 0 NAYS, 1 ABSENT AND NOT VOTING). Engrossed SB 2122 was placed on the Fourteenth order on the calendar.

2011 TESTIMONY

SB 2122

#1

BOARD OF PHARMACY
State of North Dakota

Jack Dalrymple, Governor

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

Senate Bill No 2122
Senate Health and Human Services Committee
Red River Room – State Capitol Bldg
10:45 AM – Tuesday - January 11th, 2011

Chairman Lee and members of the Senate Health and Human Services Committee the North Dakota State Board of Pharmacy introduced SB #2122 to bring language in the Century Code describing how a practitioner may request a "brand name" drug up to date with electronic prescribing.

I want to thank Brendan Joyce for handing out my Testimony as I am at a Board of Pharmacy Meeting in Fargo, North Dakota. Please ask Pharmacist Joyce any questions you have as he is prepared to answer them, although he is not delivering my testimony as a Medicaid employee he can answer your questions, as such.

The North Dakota State Board of Pharmacy has in the past reached an accommodation with Medicaid and passed the rule in the Administrative Code that you see here:

61-04-05-03. Computer transmission of prescriptions. In addition to the requirements in section 61-04-05-02, a prescription order may be transmitted from an authorized prescribing practitioner to a pharmacy under the following provisions:

1. Schedule III, IV, and V controlled substances prescriptions received via computer require an electronic signature by the authorized prescriber, as defined in North Dakota Century Code section 9-16-01, for
   the prescription to serve as the original copy.

2. Transmission of schedule II controlled substance prescriptions via computer is not allowed.

3. The required legend must appear on the practitioner's prescription screen. The practitioner must take a specific overt action to include the "brand necessary" language with the electronic transmission as set forth in subsections 3 and 4 of North Dakota Century Code section 19-02.1-14.1. For example, the practitioner or the practitioner's agent must type out "brand necessary" letter by letter.

History: Effective January 1, 2005.
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14)
Law Implemented: NDCC 28-32-03, 43-15-10(9)(12)(14)

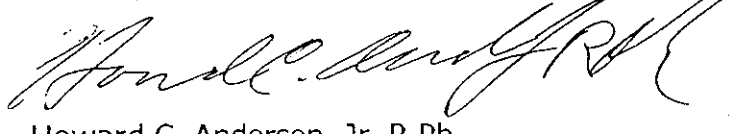
As you are well aware rules do not supersede statutes, but in this case as it was a developing area and the specific requirements for electronic prescriptions were not yet well defined, the accommodation with Medicaid, their auditors and the Board of Pharmacy served the purpose and provided guidance to physicians writing the prescriptions, pharmacists receiving the prescriptions and those auditing to be certain that the practitioner's wishes were fulfilled and we did not spend money unintentionally.

I believe it is now time to change the law, and although these things are still developing and the Drug Enforcement Administration is still in the process of issuing their final requirements for Controlled Substances Prescriptions, e-prescribing has matured to the point where I believe that changing the law is timely.

As you can imagine, this language was first developed as a way to avoid the simple check-box, brand necessary signature line while at the same time making it reasonably simple for the practitioner to require a "brand name" drug be dispensed when for good reason the patient needed the brand name drug. Payers such as yourselves, Medicare, Medicaid and insurance companies obviously do not want to pay for the "brand name" drug when more reasonably priced generics are available, unless, the patient has a specific need for the brand name drug and the additional cost is justified. As a consequence our pharmacies have accepted language which has been used in other states and in other places to say "brand necessary" or "brand medically necessary" when some states use "do not substitute" or "dispense as written".

A recent advisory form the Center for Medicare and Medicaid Services has specified that for the National Council of Prescription Drug Programs e-Scripts Standard, it will be required that "brand necessary" be inserted in a specific notes field by the prescriber and this notes field is designed so that it cannot be changed by the dispenser.

Thank you for the opportunity to provide written testimony on behalf of this bill today.



Howard C. Anderson, Jr, R.Ph.
Executive Director
ND State Board of Pharmacy

(1) The manufacturer's chief executive officer (CEO);

(2) The manufacturer's chief financial officer (CFO);

(3) An individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO; or

(4) An individual with the directly delegated authority to perform the certification on behalf of an individual described in subsections (1) through (3).

(f) *Recordkeeping requirements.* (1) A manufacturer must retain records (written or electronic) for ten years from the date the manufacturer reports data to CMS for that rebate period. The records must include these data and any other materials from which the calculations of the AMP, the best price, customary prompt pay discounts, and nominal prices are derived, including a record of any assumptions made in the calculations. The ten-year timeframe applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised pricing data subsequently submitted to CMS.

(2) A manufacturer must retain records beyond the ten-year period if both of the following circumstances exist:

(i) The records are the subject of an audit or of a government investigation related to pricing data that are used in AMP, best price, customary prompt pay discounts, or nominal prices of which the manufacturer is aware.

(ii) The audit findings or investigation related to the AMP, best price, customary prompt pay discounts, or nominal price have not been resolved.

(g) *Data reporting format.* All product and pricing data, whether submitted on a quarterly or monthly basis, must be submitted to CMS in an electronic format.

§447.512 Drugs: Aggregate upper limits of payment.

(a) *Multiple source drugs.* Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed, in the aggregate, the amount that would result from the application of the specific limits established in accordance with §447.514 of this subpart. If a specific limit has not been established under §447.514 of this subpart, then the rule for "other drugs" set forth in paragraph (b) of this section applies.

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under §447.514 of this subpart must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the—

(1) EAC plus reasonable dispensing fees established by the agency; or

(2) Providers' usual and customary charges to the general public.

(c) *Certification of brand name drugs.* (1) The upper limit for payment for multiple source drugs for which a specific limit has been established under §447.514 of this subpart does not apply if a physician certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular recipient.

(2) The agency must decide what certification form and procedure are used.

(3) A checkoff box on a form is not acceptable but a notation like "brand necessary" is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

§447.514 Upper limits for multiple source drugs.

(a) *Establishment and issuance of a listing.* (1) CMS will establish and issue listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) The FDA has rated two or more drug products as therapeutically and pharmaceutically equivalent in its most current edition of "Approved Drug Products with Therapeutic Equivalence Evaluations" (including supplements or in successor publications), regardless of whether all such formulations are rated as such and only such formulations shall be used when determining any such upper limit.

#2

MEDCO TESTIMONY IN SUPPORT OF SB 2122 WITH RECOMMENDED AMENDMENTS

Madame Chair and Members of the Senate Human Services Committee:

My name is Patrick Ward. I represent Medco Health Solutions, Inc. Medco is the world's largest mail order pharmacy, and dispenses prescriptions for 66 million Americans. We are also a pharmacy benefit manager and strive to make medicine smarter as we work with pharmacies throughout the United States to provide a drug benefit to consumers in a safe, economical, and efficient manner.

We support SB 2122 as it relates to e-prescribing and encourages use of generic drugs. However, we feel established national standards for e-prescribing required by Medicare Part D need to be taken into consideration in enacting this bill into law.

We therefore suggest the attached amendment which incorporates by reference the national standard required by Medicare Part D and by the Center for Medicare and Medicaid Services (CMS) and the National Council for Prescription Drug Programs (NCPDP).

We urge this Committee to adopt the proposed amendment to SB 2122 and then issue a Do Pass on the bill as amended.

MEDCO PROPOSED AMENDMENT TO SENATE BILL 2122
(version 11.8116.01000)

Page 1, Line 15, after "subsection" insert:

"in accord with national requirements set by CMS and NCPDP for Medicare Part D"

Page 1, Lines 15-16, overstrike:

"~~for, example, the practitioner or the practitioner's agent must type out "brand necessary" letter by letter~~"

Page 1, Line 21, overstrike:

"~~type letter by letter~~" and insert "take a specific overt action in accord with national requirements set by CMS and NCPDP for Medicare Part D"

Renumber accordingly

Pat Ward 701-223-2711

Bruce Levi
ND Medical Association

#3

SB 2122 Electronic prescriptions: Brand name specified

Is the bill designed to preclude or make more difficult a prescriber's selection of any particular covered prescription drug?

While an electronic "overt act" is appropriate in terms of indicating the prescriber's intent, the proposed statutory language requiring specific "brand necessary" and to type "'brand necessary'" letter by letter" is overly burdensome to a physician.

A prescriber's electronic medical record system may dictate how the electronic transmission communicates an "overt act."

Minnesota simply requires that the prescription is "sent by electronic transmission on which the prescriber has expressly indicated in a manner consistent with the standards for electronic prescribing" under federal law.

Internal inconsistence: Line 15-16 suggests "letter by letter" is an example, yet on line 21 is mandated.

Found "overt act" language in other states. Florida requires that "in the case of a prescription that is electronically generated and transmitted, the prescriber makes an overt act when transmitting the prescription to indicate the brand name drug prescribed is medically necessary."

Proposed Amendment to SB 2122

Page 1, line 14, replace "include the "brand name" language with the electronic" with "indicate that a brand name drug is prescribed and necessary"

Page 1, remove line 15

Page 1, line 16, remove "practitioner's agent must type out "brand necessary" letter by letter"

Page 1, line 21, replace "type letter by letter" with "indicate by overt act"

Renumber accordingly

2010 Minnesota Statutes

151.21 SUBSTITUTION.

Subdivision 1. **Generally.** Except as provided in this section, it shall be unlawful for any pharmacist or pharmacist intern who dispenses prescriptions, drugs, and medicines to substitute an article different from the one ordered, or deviate in any manner from the requirements of an order or prescription without the approval of the prescriber.

Subd. 2. **Brand name specified.** When a pharmacist receives a paper or hard copy prescription on which the prescriber has personally written in handwriting "dispense as written" or "D.A.W.," a prescription sent by electronic transmission on which the prescriber has expressly indicated in a manner consistent with the standards for electronic prescribing under Code of Federal Regulations, title 42, section 423, that the prescription is to be dispensed as transmitted and which bears the prescriber's electronic signature, or an oral prescription in which the prescriber has expressly indicated that the prescription is to be dispensed as communicated, the pharmacist shall dispense the brand name legend drug as prescribed.

Subd. 3. **Brand name not specified.** When a pharmacist receives a paper or hard copy prescription on which the prescriber has not personally written in handwriting "dispense as written" or "D.A.W.," a prescription sent by electronic transmission on which the prescriber has not expressly indicated in a manner consistent with the standards for electronic prescribing under Code of Federal Regulations, title 42, section 423, that the prescription is to be dispensed as transmitted and which bears the prescriber's electronic signature, or an oral prescription in which the prescriber has not expressly indicated that the prescription is to be dispensed as communicated, and there is available in the pharmacist's stock a less expensive generically equivalent drug that, in the pharmacist's professional judgment, is safely interchangeable with the prescribed drug, then the pharmacist shall, after disclosing the substitution to the purchaser, dispense the generic drug, unless the purchaser objects. A pharmacist may also substitute pursuant to the oral instructions of the prescriber. A pharmacist may not substitute a generically equivalent drug product unless, in the pharmacist's professional judgment, the substituted drug is therapeutically equivalent and interchangeable to the prescribed drug. A pharmacist shall notify the purchaser if the pharmacist is dispensing a drug other than the brand name drug prescribed.

Subd. 3a. **Prescriptions by electronic transmission.** Nothing in this section permits a prescriber to maintain "dispense as written" or "D.A.W." as a default on all prescriptions. Prescribers must add the "dispense as written" or "D.A.W." designation to electronic prescriptions individually, as appropriate.

Subd. 4. **Pricing.** A pharmacist dispensing a drug under the provisions of subdivision 3 shall not dispense a drug of a higher retail price than that of the brand name drug prescribed. If more than one safely interchangeable generic drug is available in a pharmacist's stock, then the pharmacist shall dispense the least expensive alternative. Any difference between acquisition cost to the pharmacist of the drug dispensed and the brand name drug prescribed shall be passed on to the purchaser.

Subd. 4a. **Sign.** A pharmacy must post a sign in a conspicuous location and in a typeface easily seen at the counter where prescriptions are dispensed stating: "In order to save you money, this pharmacy will substitute whenever possible an FDA-approved, less expensive, generic drug

product, which is therapeutically equivalent to and safely interchangeable with the one prescribed by your doctor, unless you object to this substitution."

Subd. 5. **Reimbursement.** Nothing in this section requires a pharmacist to substitute a generic drug if the substitution will make the transaction ineligible for third-party reimbursement.

Subd. 6. **Disclosure.** When a pharmacist dispenses a brand name legend drug and, at that time, a less expensive generically equivalent drug is also available in the pharmacist's stock, the pharmacist shall disclose to the purchaser that a generic drug is available.

Subd. 7. **Drug formulary.** This section does not apply when a pharmacist is dispensing a prescribed drug to persons covered under a managed health care plan that maintains a mandatory or closed drug formulary.

Subd. 8. **List of excluded products.** The Drug Formulary Committee established under section 256B.0625, subdivision 13, shall establish a list of drug products that are to be excluded from this section. This list shall be updated on an annual basis and shall be provided to the board for dissemination to pharmacists licensed in the state.

History: *(*5808-22*)* 1937 c 354 s 22; 1969 c 933 s 10; 1975 c 101 s 2; 1986 c 444; 1993 c 345 art 5 s 10; 1994 c 625 art 8 s 48,*49;* 1997 c 202 art 2 s 40; 2007 c 123 s 125-*128*

Select Year: 2010 Go

The 2010 Florida Statutes

Title XXXII
REGULATION OF PROFESSIONS AND OCCUPATIONS

Chapter 465
PHARMACY

View Entire Chapter

465.025 Substitution of drugs.–

(1) As used in this section:

(a) "Brand name" means the registered trademark name given to a drug product by its manufacturer, labeler, or distributor.

(b) "Generically equivalent drug product" means a drug product with the same active ingredient, finished dosage form, and strength.

(c) "Prescriber" means any practitioner licensed to prescribe medicinal drugs.

(2) A pharmacist who receives a prescription for a brand name drug shall, unless requested otherwise by the purchaser, substitute a less expensive, generically equivalent drug product that is:

(a) Distributed by a business entity doing business, and subject to suit and service of legal process, in the United States; and

(b) Listed in the formulary of generic and brand name drug products as provided in subsection (5) for the brand name drug prescribed,

unless the prescriber writes the words "MEDICALLY NECESSARY," in her or his own handwriting, on the face of a written prescription; unless, in the case of an oral prescription, the prescriber expressly indicates to the pharmacist that the brand name drug prescribed is medically necessary; or unless, in the case of a prescription that is electronically generated and transmitted, the prescriber makes an overt act when transmitting the prescription to indicate that the brand name drug prescribed is medically necessary. When done in conjunction with the electronic transmission of the prescription, the prescriber's overt act indicates to the pharmacist that the brand name drug prescribed is medically necessary.

(3)(a) Any pharmacist who substitutes any drug as provided in subsection (2) shall notify the person presenting the prescription of such substitution, together with the existence and amount of the retail price difference between the brand name drug and the drug substituted for it, and shall inform the person presenting the prescription that such person may refuse the substitution as provided in subsection (2).

(b) Any pharmacist substituting a less expensive drug product shall pass on to the consumer the full amount of the savings realized by such substitution.

(4) Each pharmacist shall maintain a record of any substitution of a generically equivalent drug product for a prescribed brand name drug as provided in this section.

(5) Each community pharmacy shall establish a formulary of generic and brand name drug products which, if selected as the drug product of choice, would not pose a threat to the health and safety of patients receiving prescription medication. In compiling the list of generic and brand name drug products for inclusion in the formulary, the pharmacist shall rely on drug product research, testing,

information, and formularies compiled by other pharmacies, by states, by the United States Department of Health, Education, and Welfare, by the United States Department of Health and Human Services, or by any other source which the pharmacist deems reliable. Each community pharmacy shall make such formulary available to the public, the Board of Pharmacy, or any physician requesting same. This formulary shall be revised following each addition, deletion, or modification of said formulary.

(6) The Board of Pharmacy and the Board of Medicine shall establish by rule a formulary of generic drug type and brand name drug products which are determined by the boards to demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, would pose a threat to the health and safety of patients receiving prescription medication.

(a) The formulary may be added to or deleted from as the Board of Pharmacy and the Board of Medicine deem appropriate. Any person who requests any inclusion, addition, or deletion of a generic drug type or brand name drug product to the formulary shall have the burden of proof to show cause why such inclusion, addition, or deletion should be made.

(b) Upon adoption of the formulary required by this subsection, and upon each addition, deletion, or modification to the formulary, the Board of Pharmacy shall mail a copy to each manager of the prescription department of each community pharmacy licensed by the state, each nonresident pharmacy registered in the state, and each board regulating practitioners licensed by the laws of the state to prescribe drugs shall incorporate such formulary into its rules. No pharmacist shall substitute a generically equivalent drug product for a prescribed brand name drug product if the brand name drug product or the generic drug type drug product is included in the said formulary.

(7) Every community pharmacy shall display in a prominent place that is in clear and unobstructed public view, at or near the place where prescriptions are dispensed, a sign in block letters not less than 1 inch in height which shall read: "CONSULT YOUR PHARMACIST CONCERNING THE AVAILABILITY OF A LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG AND THE REQUIREMENTS OF FLORIDA LAW."

(8) The standard of care to be applied to the acts of any pharmacist performing professional services in compliance with this section when a substitution is made by said pharmacist shall be that which would apply to the performance of professional services in the dispensing of a prescription order prescribing a drug by generic name. In no event when a pharmacist substitutes a drug shall the prescriber be liable in any action for loss, damage, injury, or death to any person occasioned by or arising from the use or nonuse of the substituted drug, unless the original drug was incorrectly prescribed.

History.—ss. 1, 7, ch. 79-226; s. 325, ch. 81-259; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 4, ch. 89-218; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 20, ch. 91-220; s. 4, ch. 91-429; s. 246, ch. 97-103; s. 4, ch. 2006-271.

#4

11.8116.01001
Title.

Prepared by the Legislative Council staff for
Senator J. Lee
January 21, 2011

PROPOSED AMENDMENTS TO SENATE BILL NO. 2122

Page 1, line 10, after ""brand" insert "medically"

Page 1, line 14, after ""brand" insert "medically"

Page 1, line 15, remove "as set forth in this subsection"

Page 1, line 15, remove "For example, the practitioner or the"

Page 1, line 16, remove "practitioner's agent must type out "brand necessary" letter by letter."

Page 1, line 21, remove "or type letter by letter"

Page 1, line 22, after ""brand" insert "medically"

Page 2, line 22, after ""brand" insert "medically"

Renumber accordingly

NDLA, S HMS

From: Lee, Judy E.
Sent: Wednesday, January 19, 2011 3:52 PM
To: NDLA, S HMS
Subject: FW: SB 2122 (e-prescription bill)
Attachments: CVSCaremark.SB2122amendment1.16.2011.docx

Please make copies of the message and attachment for our books.

Senator Judy Lee
1822 Brentwood Court
West Fargo, ND 58078
home phone: 701-282-6512
e-mail: jlee@nd.gov

From: Robert Harms [mailto:robert@harmsgroup.net]
Sent: Wednesday, January 19, 2011 2:07 PM
To: Lee, Judy E.
Cc: Anderson, Howard; 'Patrick Ward'; blevi@ndmed.com; jackmcdonald@wheelerwolf.com
Subject: SB 2122 (e-prescription bill)

Dear Senator Lee,

As you requested, Pat Ward and I have visited with Howard Anderson of the Board of Pharmacy (along with Bruce Levi of the ND Medical Association) and Jack McDonald.

It looks like we have reached an agreement on a suggested amendment, which is attached. We are ready to visit with you and members of the Senate Human Services Committee at your convenience.

Please let us know if and when you would like to visit.

Regards,

Robert W. Harms
Robert@harmsgroup.net
701-471-0959 (cell)
701-255-2841 (ofc)

On behalf of CVS Caremark

PROPOSED AMENDMENT TO SENATE BILL 2122 1/19/2011

Page 1, line 10 insert "medically" after "brand"

Page 1, Line 14 insert "medically" after "brand"

Page 1, line 15-16, remove, "For Example, the practitioner or the practitioner's agent must type out "brand necessary" letter by letter".

Page 1, line 15, insert, "The prescriber must follow national requirements as set by the Centers for Medicare and Medicaid Services and National Council for Prescription Drug Programs".

Page 1, line 21, remove "or type letter by letter" and insert, " or as described in this section, provide through electronic transmission,"

Page 1, line 22, insert "medically" after "brand"

Page 2, line 22, insert "medically" after "brand"

Robert W. Harms
471-0959

#1

BOARD OF PHARMACY
State of North Dakota

Jack Dalrymple, Governor

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

Senate Bill No 2122
House Human Services Committee
Fort Union Room – State Capitol Bldg
10:00 AM – Tuesday – March 15th, 2011

Chairman Weisz and members of the House Human Services Committee the North Dakota State Board of Pharmacy introduced SB #2122 to bring language in the Century Code describing how a practitioner may request a "brand name" drug up to date with electronic prescribing.

The North Dakota State Board of Pharmacy has in the past reached an accommodation with Medicaid and passed the rule in the Administrative Code that you see here:

61-04-05-03. Computer transmission of prescriptions. In addition to the requirements in section 61-04-05-02, a prescription order may be transmitted from an authorized prescribing practitioner to a pharmacy under the following provisions:

1. Schedule III, IV, and V controlled substances prescriptions received via computer require an electronic signature by the authorized prescriber, as defined in North Dakota Century Code section 9-16-01, for
   the prescription to serve as the original copy.

2. Transmission of schedule II controlled substance prescriptions via computer is not allowed.

3. The required legend must appear on the practitioner's prescription screen. The practitioner must take a specific overt action to include the "brand necessary" language with the electronic transmission as set forth in subsections 3 and 4 of North Dakota Century Code section 19-02.1-14.1. For example, the practitioner or the practitioner's agent must type out "brand necessary" letter by letter.

History: Effective January 1, 2005.
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14)
Law Implemented: NDCC 28-32-03, 43-15-10(9)(12)(14)

This rule is under revision as the Drug Enforcement Administration [DEA] has promised to have e-signatures in place by this fall.

(1) The manufacturer's chief executive officer (CEO);

(2) The manufacturer's chief financial officer (CFO);

(3) An individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO; or

(4) An individual with the directly delegated authority to perform the certification on behalf of an individual described in subsections (1) through (3).

(f) *Recordkeeping requirements.* (1) A manufacturer must retain records (written or electronic) for ten years from the date the manufacturer reports data to CMS for that rebate period. The records must include these data and any other materials from which the calculations of the AMP, the best price, customary prompt pay discounts, and nominal prices are derived, including a record of any assumptions made in the calculations. The ten-year timeframe applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised pricing data subsequently submitted to CMS.

(2) A manufacturer must retain records beyond the ten-year period if both of the following circumstances exist:

(i) The records are the subject of an audit or of a government investigation related to pricing data that are used in AMP, best price, customary prompt pay discounts, or nominal prices of which the manufacturer is aware.

(ii) The audit findings or investigation related to the AMP, best price, customary prompt pay discounts, or nominal price have not been resolved.

(g) *Data reporting format.* All product and pricing data, whether submitted on a quarterly or monthly basis, must be submitted to CMS in an electronic format.

§447.512 Drugs: Aggregate upper limits of payment.

(a) *Multiple source drugs.* Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed, in the aggregate, the amount that would result from the application of the specific limits established in accordance with §447.514 of this subpart. If a specific limit has not been established under §447.514 of this subpart, then the rule for "other drugs" set forth in paragraph (b) of this section applies.

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under §447.514 of this subpart must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the—

(1) EAC plus reasonable dispensing fees established by the agency; or

(2) Providers' usual and customary charges to the general public.

(c) *Certification of brand name drugs.* (1) The upper limit for payment for multiple source drugs for which a specific limit has been established under §447.514 of this subpart does not apply if a physician certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular recipient.

(2) The agency must decide what certification form and procedure are used.

(3) A checkoff box on a form is not acceptable but a notation like "brand necessary" is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

§447.514 Upper limits for multiple source drugs.

(a) *Establishment and issuance of a listing.* (1) CMS will establish and issue listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) The FDA has rated two or more drug products as therapeutically and pharmaceutically equivalent in its most current edition of "Approved Drug Products with Therapeutic Equivalence Evaluations" (including supplements or in successor publications), regardless of whether all such formulations are rated as such and only such formulations shall be used when determining any such upper limit.

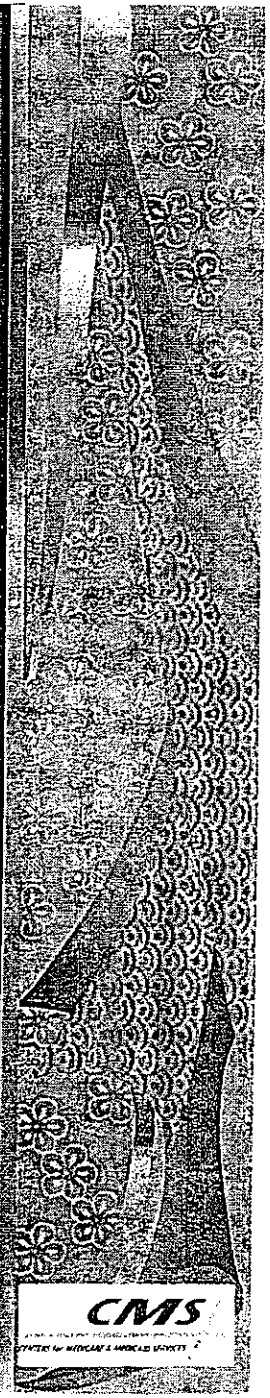
CMS Pharmacy Update

Eastern Medicaid Pharmacy Administrators Association (EMPAA) Conference

November 7-10, 2010

Nemacolin Woods Resort and SPA
Farmington, Pennsylvania

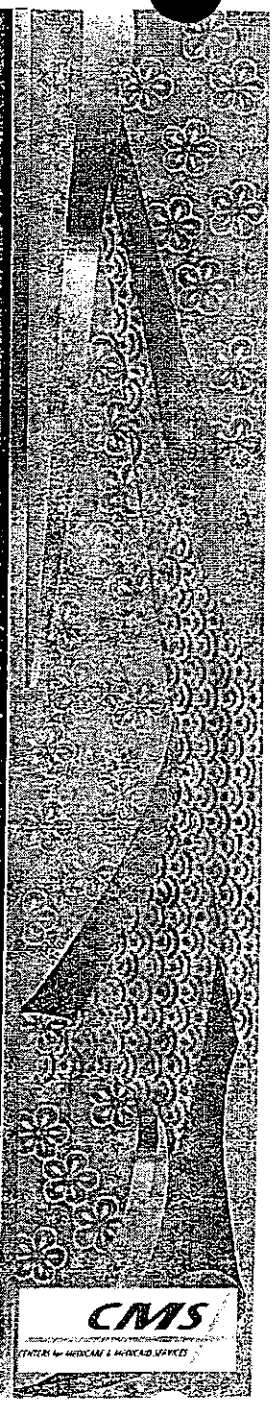
Joseph L. Fine, R.Ph, MPA
Technical Director, Pharmacy Division
Center for Medicaid, CHIP, Survey & Certification and State Operations
Centers for Medicare & Medicaid Services



E-Prescribing

Certification of Brand Name Drugs

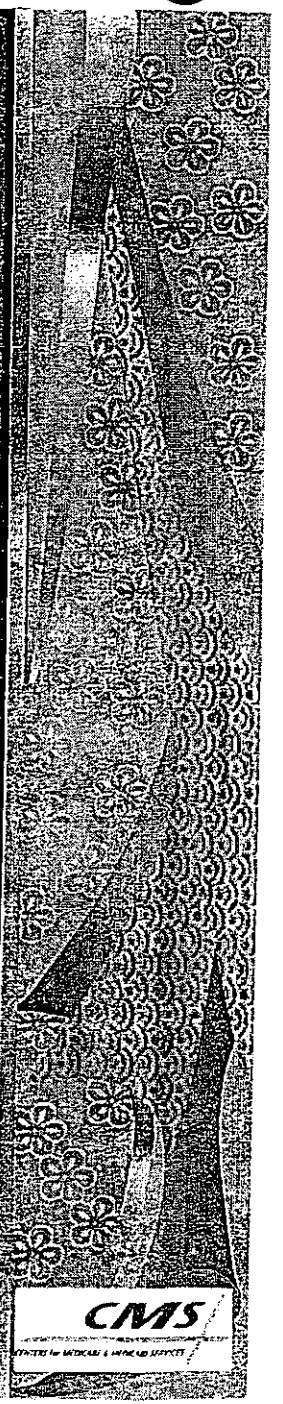
- The upper limit for payment for multiple source drugs for which a specific limit has been established . . . does not apply if a physician certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular recipient. (42 CFR Section 447.512(c))



E-Prescribing
NCPDP/CMS Proposed Solution
Brand Medically Necessary

Prescriber:

1. Place DAW = "1" on the E-Rx
2. Place in the "Note to Pharmacy" free form field (240 characters) "BRAND MEDICALLY NECESSARY"
3. Send E-Rx to pharmacy



E-Prescribing

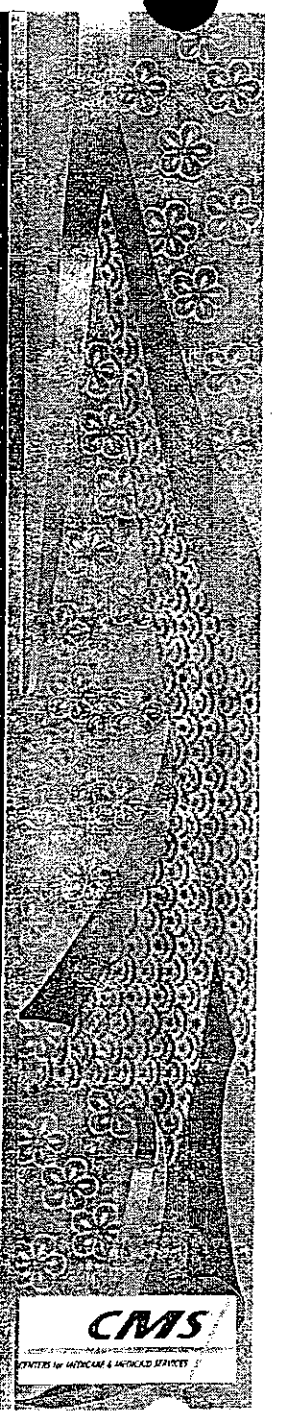
NCPDP/CMS Proposed Solution

Brand Medically Necessary

Pharmacy:

- Pharmacy receives E-Rx with DAW "1" and 'BRAND MEDICALLY NECESSARY"

NOTE: The pharmacy **cannot** make any changes to the "Prescriber Note to Pharmacy" field. If a DAW "1" appears and there is no brand necessary notation, pharmacist must contact prescriber for a new Rx!



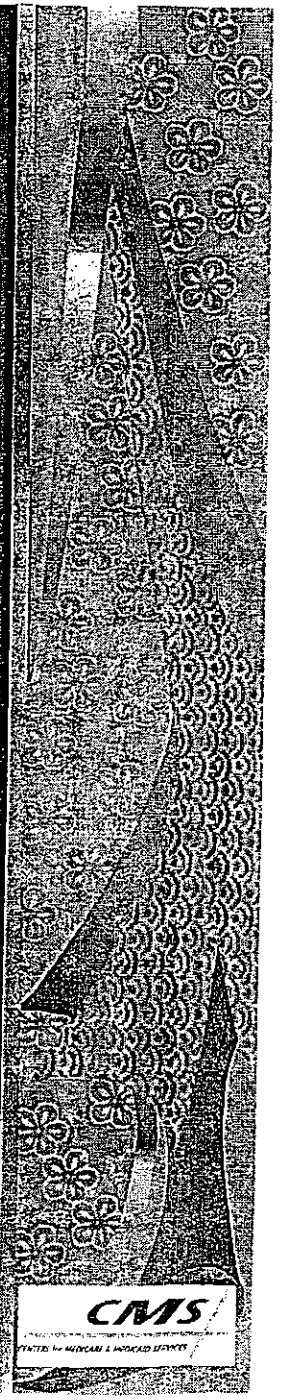
E-Prescribing

NCPDP/CMS Proposed Solution

Brand Medically Necessary

Pharmacy:

- Pharmacist fills Rx with innovator brand drug
- Pharmacist submits Rx to Medicaid as follows:
  - DAW = "1"
  - Origin Code = "3" (electronic)



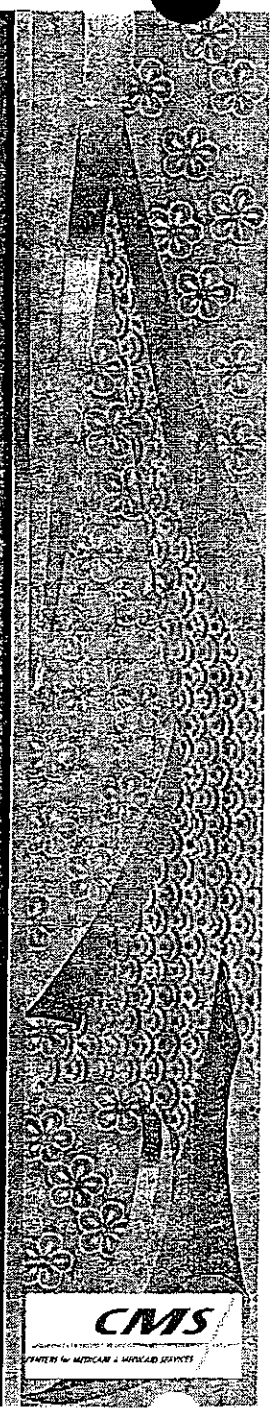
E-Prescribing

NCPDP/CMS Proposed Solution

Brand Medically Necessary

State Medicaid Program:

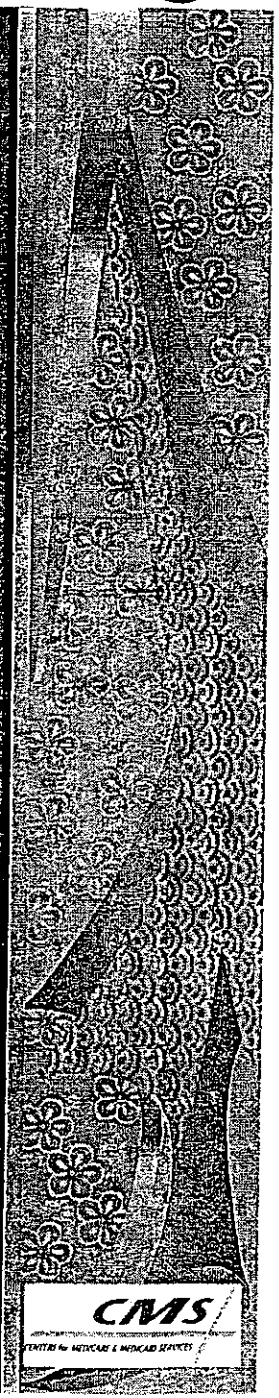
- State pays pharmacy at Brand EAC if DAW="1" and Origin Code = "3"
- State can audit prescriber's e-system to verify "Brand Medically Necessary" appears in "Prescriber Note to Pharmacy" field



E-Prescribing
NCPDP/CMS Proposed Solution
Brand Medically Necessary

State Medicaid Program:

- A State can require additional controls such as reason for Brand Necessary or Prescriber Preauthorization or additional submission of a FDA Adverse Action Report



E-Prescribing

NCPDP/CMS Proposed Solution

Brand Medically Necessary

In Summary:

- This process allows for "an electronic alternative" prescription that is acceptable to CMS for the purpose of e-prescribing

- If a pharmacy submits a DAW = "1" and an Origin Code = "3" the burden of proof redirects to the prescriber