

**2019 HOUSE INDUSTRY, BUSINESS AND LABOR**

**HB 1382**

# 2019 HOUSE STANDING COMMITTEE MINUTES

## Industry, Business and Labor Committee Peace Garden Room, State Capitol

HB 1382  
1/30/2019  
31851 (starts at 15:34 minutes)

- Subcommittee  
 Conference Committee

Committee Clerk: Ellen LeTang by Kathleen Davis

### Explanation or reason for introduction of bill/resolution:

Relating to pharmacy mail order and home delivery services

### Minutes:

Attachment 1,2,3,4

**Vice Chairman Lefor:** Opens the hearing on HB 1382.

**Chairman Keiser:** Attachment 1. Introduces the bill. If a pharmacy offers mail order delivery services, may not initiate the automatic delivery of a refill unless they have prior consent from the patient or patient's authorized representative. Goes over the bill and attachment. The drugs are paid for and not used. We want to address the cost of health care and pharmaceuticals are a major contributor to the problem, and this is one approach to that issue.

**Rep Bosch:** Did you find doctors that wrote prescriptions without an end date?

**Chairman Keiser:** There is always an end date. Periodically the doctor doesn't want to be bothered and will write the script for an automatic refill. Some go to the doctor and get renewal.

**Rep D Ruby:** Would this require them to contact me after I've called their automated renewal service?

**Chairman Keiser:** I believe that is still allowed, look at lines 8 and 9. The problem is occurring and we need to put a stop on it. By calling in, you're giving your consent which indicates the need for it.

**Rep P Anderson:** Can I tell for example CVS to just keep sending it without having to call them?

**Chairman Keiser:** I don't think you can do it, only the doctor.

**Rep P Anderson:** Can I say don't call me, just fill it.

**Chairman Keiser:** I don't think you can do that now. It's personal contact.

**Rep Schauer:** On line 8, it says "the pharmacy may not initiate delivery of a refill unless" is that strong enough words? Should it be shall not or may not?

**Chairman Keiser:** Legislative counsel considers it the same.

**Rep. Adams:** I'm on auto refill. I do have to tell them every year what I want automatically refilled.

**Rep Kasper, Dist 46:** If this does not apply, I'd like to consider an amendment to allow it. The concern I have does not address the fact that a local pharmacist should be able to do mail order, because many PBM contracts prohibit the local pharmacists to do mail order, and require they must go through the PBM's pharmacy which is out of North Dakota. That requirement takes business away from our state, the local pharmacist and the ability of the local pharmacist to have discussion and offer advice to that patient.

**Rep. P Anderson:** the local pharmacy can do home delivery.

Rep Kasper: in some cases yes, some no.

**Rep D Ruby:** I don't understand where this third party gets involved.

**Rep Kasper:** PBM contracts that are signed in some cases prohibit a 90 day fill except by mail order with the PBM. In some cases it prohibits the pharmacist from doing a 90 day fill. The local pharmacist should be able to do the same thing the mail order does from out of state.

**Rep D Ruby:** They have never indicated to me they're restricted to do anything I've asked as far as prescriptions.

**Rep Kasper:** I suggest that you talk to your pharmacist. From my experience and what I know, that is not the case.

**Rep D Ruby:** I don't know who I would talk to.

**Rep Kasper:** There is someone in the pharmacy who owns 51% or more of that company.

**Rep Richter:** Can my local pharmacist mail my prescription?

**Rep Kasper:** Because there are lawsuits pending, they can't. I would like to restate in this bill that a local pharmacist can, mail order or home deliver.

**Chairman Keiser:** Support, opposition to HB 1382.

**LuGina Mendez~Attachment 2.**

**Rep Kasper:** Are you an employee of Prime or BC of ND?

**LuGina Mendez:** Prime (inaudible, microphone not on), Minneapolis.

**Rep Kasper:** Do any of your Prime contracts require prescriptions are filled by mail order as opposed to the local pharmacist?

**LuGina Mendez:** That is a decision made by BCBS of ND. That said BCBS of ND does not have any mandatory (inaudible) for any of their members.

**Rep Kasper:** including specialty drugs?

**LuGina Mendez:** specialty drugs are different. There are specialty drugs that can only be obtained from specific pharmacies because the manufacturers have an agreement with the FDA where there's high level monitoring and so they limit the number of pharmacies that can access their medicines.

**Rep Kasper:** It's your statement that the FDA is requiring that certain specialty drugs cannot be dispensed by local pharmacists, they can only be dispensed by mail order pharmacists, isn't that what you're saying?

**LuGina Mendez:** The FDA has a program, risk mitigation strategy, RMS, the FDA has put in requirements they are concerned about side effects of a drug so they want a very close monitoring of that drug. So the manufacturers along with FDA say because they require intense monitoring, they only allow say 3 pharmacies across the nation to access our (inaudible, mic not turned on).

**REP KASPER:** What WOULD be intense monitoring?

**LuGina Mendez:** Explains the different things that are in place.

**Rep Kasper:** The monitoring means tracking.

**LuGina Mendez:** It's a risk management program. Depending on the concerns, there are certain requirements in place the FDA establishes.

**Rep Kasper:** That's limited drugs like that. Because there's hundreds of specialty drugs. Your statement is that Prime does not object to local pharmacists dispensing a number of specialty drugs just certain specialty drugs?

**LuGina Mendez:** That's not what I said.

**Rep Kasper:** Do you suggest local pharmacists should be prohibited from dispensing all specialty drugs?

**LuGina Mendez:** that's not for me to decide (inaudible)

**Rep. Kasper:** In a fully insured plan as designed by BCBS and Prime, those are sealed contracts and the PBM contracts with BC and Prime are not disclosed to the customer. So the plan designed by BC and BC owns Prime, so therefore what's in the plan is what BC & Prime to decide. Nobody ever gets to see those contracts with fully insured plan. I would like to know if you can find out, if all specialty drugs in ND are prohibited from being dispensed by local pharmacists according to the BC guidelines.

**Chairman Keiser:** Explains history from PBM's that stated specialty drugs for the mail order service were the 10 most frequently prescribed drugs in the state of ND. We stepped in because it took away a great deal of business from local pharmacies, and other problems.

**Rep Schauer:** In your statement you say unnecessary delays in drug therapy with a potential for significant damaging health outcomes. Why is this proposed legislation so burdensome it would cause significant damage to a patient?

**LuGina Mendez:** I think if we added something about auto refills that would mitigate my concerns. (inaudible)

**Chairman Keiser:** Everybody wants to control the cost. This is costing us a lot of money. How is CMS different from this?

**LuGina Mendez:** If you added the auto refill and having patient consent (inaudible)

**Chairman Keiser:** I don't care if they sign up that's my point. Sounds easy, people are going to sign up for it, and they may not need it, may not use it. That's what we have to address.

**LuGina Mendez:** It's a process where they call us and say I don't want this

**Chairman Keiser:** But it's not working. That's our dilemma. These pictures show that there are thousands of dollars of health care charges there and we can't have that, we have to correct it. That's why the language isn't just auto refill.

**LuGina Mendez:** (inaudible) There's active patient consent that's going on and they're requesting those refills. (inaudible)

**Rep M Nelson:** Does Prime watch to see if a new prescription is replacing an old unexpired prescription?

**LuGina Mendez:** Because we are adjudicating claims with all pharmacies we're able to communicate with the pharmacist at your local pharmacy. So pharmacies in our mail order pharmacy have that same messaging come to them and would engage either with your or your supplier to say, what's going on. That communication occurs because of the PBMs ability to see everything that's coming (inaudible).

**Rep M Nelson:** What you're saying is if my particular health insurer and they're using Prime, that's occurring whether I'm filling with one or various pharmacies.

**LuGina Mendez:** yes.

**Vice Chairman Lefor:** Specialty drugs with the FDA, do you have your own list where you have stated these are specialty drugs, as opposed to the FDA?

**LuGina Mendez:** I'd have to look into the contract is with BCBS.

**Vice Chairman Lefor:** I would like to see that. There seems to be a growing list of "specialty" drugs that only pharmacies who are owned by the carrier are able to deliver.

**Rep Kasper:** Communication with the PBM and the local pharmacists. Your job is to track and communicate with whoever is filling the script, so you're not just singling out the mail order PBM or excluding the local pharmacist.

**Jack McDonald~Representing America's Health Insurance Plans (AHIP):** Attachment 3

1:00:30

**Chairman Keiser:** Why does that language need to come out, the delivery of and prior consent?

**Jack McDonald:** We believe the prior consent (inaudible) and you've obtained consent by either not replying to the notice or giving consent ahead of time. (inaudible) whereas the FTC (?) says if you don't respond that's considered a positive response. We feel the word prior means you have to do something.

**Chairman Keiser:** That's the intent of the bill, you have to do something. If we were to adopt your bill can I get consent for a year or two on autorefill?

**Jack McDonald:** I can't answer that.

**Chairman Keiser:** further opposition? neutral position?

**Mark Hardy,** executive director of Board of Pharmacy: I want to stand for any legal questions in case you have any.

**Rep M Nelson:** Are you saying the specialty drugs are limited to those the FDA in their registration process limits the drugs in distribution, is that the extent of the specialty drugs?

**Mark Hardy:** That is under litigation. I think it's very clear that it extends beyond the definition of specialty drugs (inaudible) extends beyond this subset of the FDA (inaudible)

**Rep Kasper:** I would like to seek an amendment to allow for local pharmacists to do mail order and home deliver. I couldn't recall if we had that part in last session.

**Mark Hardy:** Yes, it is in law and under litigation that a pharmacy can provide services by mail or delivery. (Microphone got turned on)

**Rep Kasper:** More and more drugs are being labeled specialty drugs by PBMs and prohibiting local pharmacists from dispensing specialty drugs, is that what you are seeing that limits specialty drugs?

**Mark Hardy:** Absolutely we would stand up that any pharmacist can dispense any drugs. That issue was raised in the previous session, I don't have any firsthand knowledge but that is a concern and there are limitations placed on certain medications.

**Rep Kasper:** Are there any specialty drugs to your knowledge a local pharmacist not be qualified to provide to a patient?

**Mark Hardy:** Some pharmacies don't have the option to dispense because of the FDA.

**Vice Chairman Lefor:** What are specialty drugs as defined by the FDA versus specialty drugs defined by PBM's? Can we get a list of specialty drugs defined by the FDA? That's the only one that should carry weight.

**Mark Hardy:** I will do my best to get that to you.

**Vice Chairman Lefor:** Specialty drug, your home town pharmacies, how many would be FDA and how many made up by PBMs? Is that a growing number?

**Mark Hardy:** I think that's probably true and it's a growing market.

**Bob Harms~CVS Health lobbyist:** Attachment 4. PBM is a tool to keep the cost of prescriptions down. We are offering the amendment.

1:12:50

**Rep Kasper:** If your amendment were adopted would this require the PBM or pharmacist only receive one prior consent before continue to fill as long as the doctor continues to prescribe or is the intent that every time you must receive consent from the patient?

**Bob Harms:** The former. The consent from the patient one time.

**Rep Schauer:** Is there a problem with the medications and pills out there with the refill issue?

**Bob Harms:** I don't think it is the issue. It makes a good antidotal issue.

**Chairman Keiser:** Further questions? Anyone else with testimony? Closed the hearing. Rep. Kasper suggested an amendment, not because I oppose the principle but because that issue is already in the court. I support the bill.

**Rep. Kasper:** based on Mark Hardy's testimony I agree and no longer have that concern. I would reject Mr. Harms' amendment; his amendment would only require the consumer to give consent one time. I would move a Do Pass on HB 1382.

**Rep. Schauer:** Second.

**Chairman Keiser:** I agree with Mr. Harms that this may not be the largest contributor to the increase in health care costs. It's more than anecdotal evidence. I support this bill.

**Rep Adams:** It works well, it's up to the consumer if they want the refill.

**Chairman Keiser:** I want the patient back in the mix.

**Rep Kasper:** Most of the mail orders are for the long term drugs, like a 90 day script with 3 refills for example. It's the choice, this gives the choice.

**Rep P Anderson:** So this gives the choice of auto fill without them calling?

**Rep Kasper:** What this says you will be notified and you have that choice.

**Chairman Keiser:** The physician will start thinking about how long the script is written for. If this is passed. Keeping the patient engaged is not a bad thing.

**Rep D Ruby:** I did like the inclusion of the words "an auto refill". If you have a 30 day, physicians might now extend to a 90 day. It was going after the auto refills.

**Chairman Keiser:** It doesn't matter. If you are not on auto refill, you will be contacted.

**Rep D Ruby:** If you have a 3 or 4 refill, that's not considered an auto refill?

**Chairman Keiser:** I'm not sure you can say that. You have to be contacted every time.

**Rep Kasper:** It makes me comes in. This bill makes the customer more engaged.

**Rep P Anderson:** We are not concerned of being outside of the FTC negative option rule?

**Chairman Keiser:** We are a sovereign state. I think this is closer to what CMS is doing. CMS is outside the rule right now, but they recognize the cost driver portion of this.

We have a motion and a second for a Do Pass on HB 1382.

Roll call vote 10 yes 3 no 1 absent. Motion carried. Rep. Laning is carrier.

Date: Jan 30, 2019

Roll Call Vote #: 1

2019 HOUSE STANDING COMMITTEE  
ROLL CALL VOTES

BILL/RESOLUTION NO. 1382

House \_\_\_\_\_ Industry, Business and Labor \_\_\_\_\_ Committee

Subcommittee

Amendment LC# or Description: \_\_\_\_\_

Recommendation

- Adopt Amendment
- Do Pass     Do Not Pass     Without Committee Recommendation
- As Amended     Rerefer to Appropriations
- Place on Consent Calendar

Other Actions     Reconsider     \_\_\_\_\_

Motion Made by Rep Kasper    Seconded By Rep Schauer

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser	x		Rep O'Brien	Ab	
Vice Chairman Lefor	x		Rep Richter	x	
Rep Bosch		x	Rep Ruby	x	
Rep C Johnson	x		Rep Schauer	x	
Rep Kasper	x		Rep Adams	x	
Rep Laning	x		Rep P Anderson		x
Rep Louser	x		Rep M Nelson		x

Total (Yes) 10 No 3

Absent 1

Floor Assignment Rep. Laning

**REPORT OF STANDING COMMITTEE**

**HB 1382: Industry, Business and Labor Committee (Rep. Keiser, Chairman)**  
recommends **DO PASS** (10 YEAS, 3 NAYS, 1 ABSENT AND NOT VOTING).  
HB 1382 was placed on the Eleventh order on the calendar.

**2019 SENATE HUMAN SERVICES**

**HB 1382**

# 2019 SENATE STANDING COMMITTEE MINUTES

Human Services Committee  
Red River Room, State Capitol

HB 1382  
3/18/2019  
Job # 33841

- Subcommittee  
 Conference Committee

Committee Clerk: Justin Velez

## Explanation or reason for introduction of bill/resolution:

Relating to pharmacy mail order and home delivery services.

## Minutes:

Attachments #1-4

## Madam Chair Lee opens the hearing on HB 1382.

### Representative George Keiser, District 47 introduces HB 1382 and provides testimony.

Testimony is as follows: I bring you a really short bill but not one without some controversy of course. It does deal with mail order and prior delivery consent, it simply says that if a pharmacy offers a prescription to home delivery and mail order delivery services the pharmacy may not initiate the delivery of retail without consent from the patient or the patients authorized care giver. If you would allow me Madam Chair Lee to discuss another bill in relation to this to try and put this into perspective. I'm not sure if your committee had the bill from the insurance department relative to the re-insurance program that is being proposed for the individual group market.

**Madam Chair Lee:** That was in IBL.

**Representative Keiser:** To just put it in perspective, the fiscal note that was attached to that bill is 37.5 million dollars for the next biennium and I'm not certain what the senate will do with that, the house did pass the bill. In the bill there were two provisions that were important for you to understand. One, they put a sunset on it because the projection over the next 10 years is almost one billion dollars for the state of North Dakota directly out of the general fund. In addition to that we put a study requirement for a study to shall consider because we need to begin to address what is driving healthcare, the cost in the state of North Dakota. This bill is an attempt to drive that. I have handed out to you just three pictures (**Please see Attachment #1**), with mail order and that process. If there is an auto refill, what they have set up I assume is so many days outside of that script being complete that something triggers auto-refill and sends that script out. As you can see in these pictures, the first one is from an unidentified pharmacy in central North Dakota, a patient brought in these scripts after they tried to cancel their auto-fill three or four times. This is happening for a variety of reasons I suspect, with the older population, if you send them something that they may use either now or sometime in the future they may very well keep it. In these cases, it became a concern

and we are trying to take them back. What the bills does is it simply says is that nowhere and other auto-refill programs should act like your pharmacy does. I may have a refill at my pharmacy but if I call them they will refill it but I have to go and pick it up, I have some responsibility in that situation and that is that I have to pick it up. Every case when I have done that, the pharmacist has asked me how it was working, if there were any special instructions that said remember you need to take this with food or whatever. The pharmacist has been serving in my best interest. In this system there is no contact like that. In this bill it says you can still have auto-fill and have mail order but we need to have some contact. These medications should have never been sent, and I argue that if they had contacted the people and said you are coming up for your auto-refill do you need it, they would have said no I stopped taking the medication. There was significant opposition to this, AHIP (American Health Insurance Plans) opposed it, they are coming from it from an ease of administration for the insurance companies and the relationship with their own individual premiums. I would argue that if we don't really begin to address what is driving healthcare costs, and clearly this is. These are un-needed, un-used, expensive medications in some cases and it is something we can do legislatively. I will yield for any questions.

**Senator Anderson:** We have a prescription donation program in the state and when we first started that program the first donation was 23,000 dollars of a medication from a patient in Stanley who had received it from the mail-order after he expired, he was in hospice. This would reduce the donation to that program do you know that.

**Representative Keiser:** Yes, I do, but I also realize that there should be a different and better vehicle for that.

**Senator K. Roers:** One of the things that we struggle with is medication compliance do you have any concerns for medication compliance because you're now putting the onus on the patient to remember to re-order when they do need it and it's a drug that they the consistent dose and then they forget to order it and there is a delay. Do you worry that there is a negative effect on this?

**Representative Keiser:** Absolutely not, I think that is a bogus argument and I will tell you why because what pharmacy benefit manager doesn't want to refill and bill for this, that is their business. What you are suggesting is that the pharmacy is going to say when the auto-refill comes up they are going to say I'm not going to call them, I'm going to lose that business. That doesn't make any sense.

**Senator K. Roers:** I will respectfully disagree.

**Madam Chair Lee:** I don't think we have any control over the VA I see it's a remarkable example of stuff that is used up.

**Representative Keiser:** I just took a couple of samples to show you that this is a significant problem and is contributing to the cost of healthcare, when these prescriptions are filled and not being utilized, someone is paying for them.

**Senator Anderson:** The donation that I mentioned was a VA eligible patient but they were using a contracted pharmacy.

**Madam Chair Lee:** If it was a specialty drug then we got a lot of money from that too. You just keep bringing us Sophie's choices here.

**Representative Keiser:** You can continue to say we are not going to do anything or we can continue to say, what can we do. I would make the argument that if this bill passes we will impact the cost of health care.

**Madam Chair Lee:** What is the bill with the study.

**Representative Keiser:** It's the reinsurance program. The president by executive order eliminated in the ACA (affordable care act) the subsidization of high risk health care plans that had an over concentration of high risk patients, when they did that, it has had a significant impact especially in the individual market of ND.

**Madam Chair Lee:** When you talked about auto-refills because I would think half the people take something on daily basis, I always have to call and ask to refill it and the voicemail program will say it is too early and I can't do it yet, it's not automatically done but when I call they say it's too early.

**Representative Keiser:** If I go to my pharmacists they do the same. I have not received these automatically in the mail. What I am trying to suggest is an appropriate strategy.

**(11:50-17:15) Dr. LuGina Mendez-Harper, Pharmacists for Prime Therapeutics.** Testifying in opposition to HB 1382. Please see **Attachment #2** for written testimony.

**Senator Hogan:** How are consumers educated about the easy opt out program and how is that communicated and how often is it used?

**Dr. Mendez-Harper:** Typically, when you get your shipment you will have your receipt and how to dispose it. There is a number on the bottle to the pharmacy we have it on the website.

**Senator Hogan:** I get a lot of that, most of it is in tiny print and hard to understand. Do you know how many people are opting out?

**Dr. Mendez-Harper:** No, but I can get you that information.

**Madam Chair Lee:** I got a lot of those in the last week and it's not that I don't think we understand it, I just don't have the time to read it and I knew it would put me right to sleep.

**Senator Anderson:** There is obviously medication being sent to these patients that they don't want some of them said they tried to opt out. Do you have a solution to what we are seeing?

**Dr. Mendez-Harper:** Other than the programs that are in effect now.

**Senator Anderson:** Well apparently the ones that we have now aren't working. I think what Representative Keiser is looking for here is very similar to what the FTC requires when I

order a pair of boots when they say is it okay for us to send the boots, I say ok, and they send the boots. What he is asking for here is a similar thing, do we have something that says do you want the prescription, and not buried in the contract and not in the contract that comes with the original insurance plan that is 57 pages and says if you want to opt out you can. What we want here is some kind of contact whether its e-mail or whatever saying that the prescription is ready to be sent out in a few days and if they don't respond then you send it. If you don't contact them then they don't have an option to pot out.

**Dr. Mendez-Harper:** I agree with you, we do have a program such as that where they will send out an e-mail or a text depending on what form of communication suits the patient we will say this is up for refill and, are you ready to receive the refill. My concern with the words on the paper for this legislation is that we have to obtain consent in every single instance even if the patient sent us the prescription. The patient went online and requested the prescription we would still have to contact them and say; I know you just ordered this prescription with us but I want to make sure that we have your consent to fill it. I'm responding to the words on the paper.

**Senator Anderson:** Here we can look to the FTC thing here if you send them that notice silence means consent, but if you don't send them the notice then you're in violation, that is what it is saying here.

**Senator K. Roers:** Amazon does that for me, I have a regular routine of things sent to me and when its ready to be delivered it lets me know when it will be there and it is up to me to cancel it if I don't want it.

**Dr. Mendez-Harper:** Okay, they can still send it as long as you don't cancel it?

**Senator K. Roers:** Right.

**Dr. Mendez-Harper:** Oh okay, that is fine.

**Senator Anderson:** It's an easy out, if they remain silent then they will get their prescription.

**Dr. Mendez-Harper:** That completely addresses my concern about continuity care as long as we can get them their medicine so that they are not missing doses.

**Senator Anderson:** It does require then that you change your process a little bit, seven days' notice or whatever works. It's just a notice to the patient that they can respond to if they want to cancel it.

**Madam Chair Lee:** It's nice to have a potential solution that potentially pops up in conversation. Any further opposition?

**(23:45-25:08) Emily McGann, CVS Health.** Testifying in opposition on HB 1382. Testimony is as follows: I just wanted to echo the concerns that were previously addressed by my colleague at Prime Therapeutics. I agree with you that there might be a solution in place but I'll say in the meantime adherence and patient outcomes are of the utmost importance to us

at CVS health and we want to make sure that patients get the medications that they need in the most convenient way possible.

**(25:15-27:40) Jack McDonald, on behalf of Americas Health Insurance Plans (AHIP).** Testifying in opposition of HB 1382. Please see **Attachment #3** for written testimony. Also please see **Attachment #4** for additional testimony from Lauren Rowley, Vice President of State Affairs for the Pharmaceutical Care Management Association.

**Senator Anderson:** If I get a pair of boots I can send the boots back, and they can sell them to someone else. If I get a prescription in the mail and send them back, they tell me that they can't then take the medication back after they have been delivered. It's obviously not working in all these cases. Now, these FTC things that you passed out says that when you send me a shipment you send me a notice and I have the option to cancel it. What we are looking at right now is I get a prescription that has 12 refills for the year the mail order operation says that if I send them that prescription it is automatic approval for those. What we are saying here is that you need to tell us every time you are about to send out a shipment so that I have the option to accept or decline.

**Jack McDonald:** I don't really agree with that because like I said, we do conform with the FTC now that says we notify them that they have to opt out.

**Senator Anderson:** What we are saying is that one notification is not enough. Each time you send me a prescription I need to say that I want it or not.

**Jack McDonald:** Not every prescription is for a year either.

**Senator Anderson:** Some are for two years.

**Senator K. Roers:** I don't read this bill as this negative opt out, I don't think this is as explicit as that. Would you be willing to take a look at this negative option rule, you could find some language that could make this the law. I'm reading this as the patient must contact you first.

**Jack McDonald:** Yes, I would certainly take a look at that.

**Senator Hogan:** The easy opt out is the language that I struggle with. I had a prescription with my doctor asked me to change and it took me three calls to get the prescriptions to stop. I think I'm relatively smart but it was the third time that they sent me a notice that my prescription was ready, I had canceled it three months ago. I think the easy opt out is the piece that worries me because I think sometimes its not that easy.

**Senator Anderson:** The boots I paid for and the prescription I probably didn't.

**Madam Chair Lee:** If you would prefer to not get involved with drafting the language it's okay for you to say so but if you are willing to participate in this prescription we would appreciate that.

**Jack McDonald:** I will see what we can do with that.

**(32:59) Mark Hardy, Executive Director of the North Dakota Board of Pharmacy.** Offering neutral testimony on HB 1382. Testimony's is as follows: I don't have any written testimony from a policy perspective but, I would be more than happy to answer any questions the committee may have. The only comment that I would make would be all appreciate if it was the pharmacists talking to the patient each time on those prescriptions and I think those issues would be addressed.

**Madam Chair Lee:** I don't know if we could legislate for the pharmacists to do it. Is that the highest and best use of the pharmacist's time to make the call directly? Wouldn't you think that the pharmacy tech or someone on the latter of practice so to speak would be able to have that contact with the patient. I don't think that they would have to speak to a doctor or pharmacists just to confirm a prescription.

**Mark Hardy:** I meant it in the context of the consultation upon receiving the prescriptions.

**(34:04) Jack McDonald:** It started out that i used to get a phone call from the pharmacists and now I get e-mails and now they have text. It's not mail order but it kind of is because it is automatically going to be renewed when I go to pick it up so there are efforts being made.

**Madam Chair Lee:** I am fond of e-mail; I am not fond of text for those types of things.

**Madam Chair Lee closes the hearing on HB 1382.**

# 2019 SENATE STANDING COMMITTEE MINUTES

**Human Services Committee**  
Red River Room, State Capitol

HB 1382  
3/26/2019  
Job #34223

- Subcommittee  
 Conference Committee

Committee Clerk: Justin Velez

## **Explanation or reason for introduction of bill/resolution:**

Relating to pharmacy mail order and home delivery services.

## **Minutes:**

Attachment #1

**Madam Chair Lee opens the discussion on HB 1382. Please see Attachment #1 for proposed amendments from Robert Harms, CVS.**

**Madam Chair Lee:** HB 1382 is the bill which talks about mail order pharmacy and home delivery.

**Senator Anderson:** I think that the amendments that Mr. Harms presented here is attempting to go back to square one. He is going to use the excuse that because you sent the original prescription you can send it to that and all the refills or since you signed a contract that says you have health insurance you're going to go back so, I would suggest that his amendment is okay if we insert an "a", the pharmacy obtains prior written consent from the patients or patients authorized representative on each original prescription or refill, and that will solve both problems.

**Madam Chair Lee:** So, in the addition after line 8, it would then be "a pharmacy obtains prior written consent from the patient or the patients authorized representative" and then add "on each original prescription or refill".

**Senator K. Roers:** If we say written, if they have an electronic process would that still.

**Senator Anderson:** Yes, that is fine. It says prior consent; it doesn't say written.

**Senator K. Roers:** You said written.

**Senator Anderson:** Oh did I? Okay, I think prior consent is fine. We don't need written, electronic is fine. A lot of these operations they even have where you can call in and they record all the calls so they have that record so even a voice is fine. As long as a patient knows it is coming, if they ignore it than they get it. That is what most people will do if it's

okay with them that it is coming or otherwise like Senator Hogan said, we shouldn't have to call three times to get the same change.

**Madam Chair Lee:** Mr. McDonald or Mr. Harms does either of you have a brief comment on the amendments?

**Robert Harms, CVS:** Mr. McDonald and I are not sure how the amendment would read. I don't think we have a problem with it if it leaves section B in, I think it will be fine. The subsection A would read "the pharmacy obtains prior consent from the patient of the patients authorized representative on each original prescription or refill". I think we can live with that.

**Madam Chair Lee:** Any questions for Mr. Harms? If not, thank you.

**Senator Anderson:** I move the **AMENDMENT**.  
**Seconded by Senator O. Larsen**

**Madam Chair Lee:** Any further discussion on the amendment? If not, please call the roll.

**ROLL CALL VOTE TAKEN**

**6 YEA, 0 NAY, 0 ABSENT**  
**MOTION CARRIES TO ADOPT AMENDMENT**

**Senator Anderson:** I move a **DO PASS, AS AMENDED**  
**Seconded by Senator O. Larsen**

**ROLL CALL VOTE TAKEN**

**6 YEA, 0 NAY, 0 ABSENT**  
**MOTION CARRIES DO PASS, AS AMENDED**  
**Senator Anderson will carry HB 1382 to the floor.**

**Madam Chair Lee closes the discussion on HB 1382.**

March 26, 2019

SK  
3/26  
181

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1382

Page 1, line 6, remove " - **Prior consent**"

Page 1, line 7, replace "If a" with "A"

Page 1, line 7, after "pharmacy" insert "that"

Page 1, line 7, remove the underscored comma

Page 1, line 8, remove "the pharmacy"

Page 1, line 8, remove "not"

Page 1, line 8, replace "unless the pharmacy" with "if:

a. The pharmacy"

Page 1, line 9, after "representative" insert "for each renewal prescription or refill; or

b. After notice of a forthcoming delivery, the patient does not inform the pharmacy the patient does not want the refill"

Renumber accordingly

**2019 SENATE STANDING COMMITTEE  
 ROLL CALL VOTES  
 BILL/RESOLUTION NO. 1382**

Senate Human Services Committee

Subcommittee

Amendment LC# or Description: 19.0959.01061

- Recommendation:  Adopt Amendment  
 Do Pass     Do Not Pass     Without Committee Recommendation  
 As Amended     Rerefer to Appropriations  
 Place on Consent Calendar  
 Other Actions:     Reconsider     \_\_\_\_\_

Motion Made By Sen. Anderson    Seconded By Sen. O. Larsen

Senators	Yes	No	Senators	Yes	No
Sen. Judy Lee	X		Sen. Kathy Hogan	X	
Sen. Oley Larsen	X				
Sen. Howard C. Anderson	X				
Sen. David Clemens	X				
Sen. Kristin Roers	X				

Total (Yes) 6    No 0

Absent 0

Floor Assignment \_\_\_\_\_

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



REPORT OF STANDING COMMITTEE

**HB 1382: Human Services Committee (Sen. J. Lee, Chairman)** recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). HB 1382 was placed on the Sixth order on the calendar.

Page 1, line 6, remove "**Prior consent**"

Page 1, line 7, replace "If a" with "A"

Page 1, line 7, after "pharmacy" insert "that"

Page 1, line 7, remove the underscored comma

Page 1, line 8, remove "the pharmacy"

Page 1, line 8, remove "not"

Page 1, line 8, replace "unless the pharmacy" with "if:

a. The pharmacy"

Page 1, line 9, after "representative" insert "for each renewal prescription or refill; or

b. After notice of a forthcoming delivery, the patient does not inform the pharmacy the patient does not want the refill"

Renumber accordingly

**2019 CONFERENCE COMMITTEE**

**HB 1382**

# 2019 HOUSE STANDING COMMITTEE MINUTES

## Industry, Business and Labor Committee Peace Garden Room, State Capitol

HB 1382  
4/8/2019  
34727

- Subcommittee  
 Conference Committee

Committee Clerk: Ellen LeTang

### Explanation or reason for introduction of bill/resolution:

Pharmacy Mail order & home delivery services.

### Minutes:

Attachment 1, 2

**Chairman Kasper:** The Senate made substantial changes in the bill. We would love to hear the changes you made & why you did so.

**Sen H Anderson:** Attachment 1. In the negotiations in the Senate, we looked at some of the FTC language, silence means consent, we modified the language. In a you can see “for each renewal prescription refill”, that wasn’t the amendment that was originally brought to us. So we added that language to a. We used the FTC language in b, to say after notice of a forth coming delivery, the patient does not inform the pharmacy, the patient does not want the refill. That means that the patient must have to contact them. We understand that the house wasn’t happy with that but we are willing to look at some changes.

**Rep Lefor:** That’s what we wanted to know was the reason for it. The concern we had that sometimes delivery would be made, they didn’t request the refill & they were gone. We were looking for communications between the patient & the pharmacy.

**Sen H Anderson:** There were some that had the same concerns. Some pharmacies say that they do try to contact the patient but on the first contact, like 15 or 20 percent of people they can actually get a hold of when they try to call. If they do a second attempt, maybe it rises to 25 or 30 percent but there still is that 70 percent that they can’t get a hold of.

There was some concern that a patient might end up without medication. The mail-order operation, that they knew that the patient wanted it & that was the original intention of the bill. I read some information from FTC, that there are 4 different provisions, the last provision was that they need to provide a refund if the medication was sent & the patient didn’t want. That’s a provision that I like & we can do some more work it more explicit.

**Chairman Kasper:** My response, it’s still a cost to the health plan. I’m going to assume that the PBM has to provide the refund to the patient, that they could still charge the plan?

**Sen H Anderson:** I think we could change some language so that they had to pay back anything the patient paid & they had to reimburse the plan. I think we should put both in there.

**Rep Adams:** Reading on our original one the new one, it says that they not initiate the delivery of a refill, but on the new one it says each refill. I think that would get too cumbersome. I think it would be hard for both the pharmacy & the patient.

**Sen H Anderson:** Everybody who has an auto refill program now, somehow has the patient opt in for that. However, that's not solving the problem we have now. The plan is paying for that & as long as the pharmacy & the PBM are getting paid for that, there is no incentive to stop the prescription. Those are the things that we want to get stopped. The purpose is to stop those payments.

**Rep Lefor:** Is there any appetite to go back to the House version or is there some other concern that needs to be addressed?

**Sen H Anderson:** We might like the House version because it would give the impression that they always restock the patient. However, we are inviting the FTC's intervention to say that it isn't ok. If we could fix it to make it clear & had some perimeters, I think that would be better. We still have to answer those pharmacies. I think if we put out a few perimeters in there to make sure that at least it only happens once.

**Vice Chairman Lefor:** Why is the concern of the FTC? Would an amendment that would put us in compliance with that?

**Sen H Anderson:** I could prepare that language & bring it in.

**Chairman Kasper:** Item B on the senate version, it suggests that we consider after notice of a forthcoming delivery for each renewal prescription or refill, the patient does not respond to more than one attempt by different means to obtain consent prior to each mailing or delivery. it would be a phone call, email or text. If you require one or more attempts & no one answers, the prescription is filled. It costs the plan & the subscriber. Those are the areas of concern to myself. What authority does the FTC have in ND? Is it only on ERISA plans, I'm not aware of any FTC oversight on PBMs.

**Sen H Anderson:** They don't they have a lot of authority except when it comes to ERISA plans or Medicare Part D plans. Personally, I'm ok with the language, but some pharmacies are going to be concerned. They are going to make efforts to contact the patients. They may have to start earlier.

**Chairman Kasper:** My thought will be that we will adjourn & look at creating some amendments.

**Sen H Anderson: Attachment 2.** If we could look at this language, under number 2 on Page 2 of the handout is new information. The kicker there is providing the refund.

**Chairman Kasper:** I would be concerned with the “no affirmative consent prior to shipping or delivering each new or refill prescription if a company by the following”. There is all those outs that I’m concerned with.

**Chairman Kasper:** Closes the hearing HB 1382.

# 2019 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee  
Peace Garden Room, State Capitol

**HB 1382**  
4/10/2019  
34645

- Subcommittee  
 Conference Committee

**Committee Clerk:** Ellen LeTang

## Explanation or reason for introduction of bill/resolution:

Relating to pharmacy mail order and home delivery services.

## Minutes:

Attachment 1, 2

**Chairman Kasper:** Opens the conference committee hearing on HB 1382. I just received the amendment, so I haven't gone over them. Sen H Anderson would you introduce your Senate amendment.

**Sen H Anderson:** Attachment 1. Goes over his amendment which is attachment 1.

**Vice Chairman Lefor:** For the role of the PBM, should there be wording that says "the PBM may not charge the health plan". How does that relationship work? **Attachment 2.** Under A, number 2, I have quotes "The pharmacy may not charge the patient for the unwanted refill & within 30 days of the notification of the pharmacy, the pharmacy automatically shall refund to the patient all payment made by the patient relating to the unwanted refill, including a copayment". That takes care of the relationship between the patient & the pharmacy.

What about the relationship between the pharmacy & the PBM? My intent under b was going to put, "the pharmacy or pharmacy benefit manager may not charge the health plan for the unwanted refill... Is that right?"

**Sen H Anderson:** Whether it's a PBM own pharmacy or independent in ND, the pharmacy is the one that is sending the bill. I could say the PBM might charge the plan. I'm not sure whether there is language needed in there or how the contract works.

**Vice Chairman Lefor:** What I'm trying to avoid here is where the pharmacy gets stuck in the middle. The pharmacy gives the refund, but the PBM does not give the refund to the pharmacy.

**Sen H Anderson:** Maybe we just need to include language "the pharmacy and/or pharmacy benefit manager".

**Vice Chairman Lefor:** What I would do under the b is change it to “the pharmacy benefit manager or the pharmacy”. My point is that it’s being done properly through all the channels. If it’s an unwanted prescription, the pharmacy refunds it. The pharmacy benefit manager or health plan bill the pharmacy. That’s what I’m trying to do here, so that nobody pays for it.

**Chairman Kasper:** I’m looking for the assurance that the PBM does not charge the insurance plan.

**Vice Chairman Lefor:** I would change my amendment, under b to reflect adding the words after, “pharmacy”, I would add “or PBM” & the same thing on the 3<sup>rd</sup> line under b.

**Sen H Anderson:** Under d in my amendment, I used the term “plan sponsor”.

**Chairman Kasper:** If it’s the plan sponsor, if it’s a fully insured plan, really doesn’t have much authority or the PBM. It’s the insurance company that negotiates with the PBM. I would be concerned about that language. It could be an addition to it.

**Sen H Anderson:** What the language says here is the refund needs to go to the plan sponsor as well as the patient.

**Chairman Kasper:** Now the word is “pharmacy” if you are looking at d on your amendment. What if it’s the PBM?

**Sen H Anderson:** Rep Lefor will take care of that.

**Rep Lefor:** What I’m asking the committee is that I were to change b to the following, “the pharmacy or PBM may not charge the health plan for the unwanted refill...”. Does that cover what we are after here?

**Chairman Kasper:** What about the co-pay, is it that the patient had not accepted it?

**Rep Lefor:** Correct & under a, including the co-payments. So they have to refund that.

**Chairman Kasper:** Any people in the room that want to make a comment?

**Robert Harms~CVS Health:** (Hard to hear, didn’t turn on the mike) My sense is that you are on the right track, they would be separate contracts. The first cut is on the right track. They will have a contract I wouldn’t worry about that piece.

**12:20**

**Chairman Kasper:** Again, my concern is with the fully insured plan, the contract is with the employers not the PBM. The contract is with the insurance company.

**Robert Harms:** I agree with that structure.

**Chairman Kasper:** My concern is that in here, in all this process, the paperwork gets shoved up to PBM level. Underneath the PBM, with the pharmacy & mail order pharmacist, all these

things occur, but the PBM should be prohibited from charging the plan because it's been returned. I almost think that we should have a c that deals with the PBM responsibility of what they can & cannot do.

**Robert Harms:** (Inaudible).

**15:15**

**Chairman Kasper:** The unspoken, is that the PBM could potentially charge the plan or pharmacist for the unwanted prescription because they are the ultimate arbitrator.

**Robert Harms:** If I'm the pharmacist & I have a contract with the PBM. I'm only supposed to get paid for the dispensation under the contract. If I make a mistake, I shouldn't get paid for that.

**Chairman Kasper:** With the PBM, because there has been a prescription sent out that was an error because the PBM was in charge of the process, would the PBM have the ability to charge the plan for that unwanted prescription.

**Robert Harms:** I don't know the answer to that.

**Sen Hogan:** I like this amendment in general, perhaps we should make the effective date for Jan 1, 2020 because that is generally the contract date.

**Sen Clemens:** I understand the concern about the insurance but I'm have a problem going beyond the two people that are actually involved in the transaction. I'm hesitant to go beyond the pharmacy, that's their decision. If there is an issue, they need to tighten up on their policy with the people that they are serving.

**Rep Lefor:** If you have a refill, I believe that we should involve all parts because PBM's are involved in this. There could be a situation that the PBM would change the health plan & the pharmacist loses. I'm concerned that this could happen. We are asking for a refund & the patient isn't paying for it. We are talking about contractual relationships.

**Mark Harding~ND Executive Board of Pharmacy:** I think what you are getting at is that you want the claim adjudicated to be reversed.

**Chairman Kasper:** The unwanted fill & patient didn't give consent. It's been filled & shipped, it need to be reversed from the perspective of all the paperwork & crediting, so that the patient & pharmacist doesn't pay. The PBM cannot charge the plan for a refill that is not wanted. Another concern, they cannot deal, not in good faith, with the pharmacist. I want to make sure that even we have the language right to cover those incidences.

**Sen Hogan:** I'm curious if this could be done administratively?

**Mark Harding:** You are talking about two perspectives. The first perspective is the pharmacy where the patient goes to the pharmacy & they reverse the claim. The flip side, would the PBM, for that claim, how would they reimburse that the plan sponsor?

**Sen Hogan:** It's not procedurally & administratively a huge issue?

**Mark Harding:** From the pharmacy perspective, no. From the PBM side, I don't want to speak for them.

**Rep Lefor:** What I'm trying to do is treat everyone equally. Why would we leave someone out of the equation saying PBMs, it's ok for you not to be here?

**Mark Harding:** I think that's justifiable, it's a matter of the language.

**Rep Adams:** I get an unwanted refill, is the pharmacy required right away opt me out of a refill or do I fill out more paper work?

**Mark Hardng:** It depends on the process.

**Sen H Anderson:** Once it's out of their control, they can't dispense again. As part of the incentive, the pharmacy will pay more attention.

**Vice Chairman Lefor:** How would the committee feel if I updated the wording on the amendment?

**Chairman Kasper:** That was what I was going to suggest. Closes the hearing.

# 2019 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee  
Peace Garden Room, State Capitol

HB 1382  
4/12/2019  
34715

- Subcommittee  
 Conference Committee

Committee Clerk: Ellen LeTang

## Explanation or reason for introduction of bill/resolution:

Pharmacy Mail order & home delivery services.

## Minutes:

Attachment 1

**Chairman Kasper:** We need to continue our discussion on amendments.

**Vice Chairman Lefor:** I tried to fashion all the comments into an amendment. (Attachment 1.) Reads the amendment.

**2:30**

**Chairman Kasper:** Are there any questions? Seeing none, is there a motion?

**Rep Lefor:** Moves that the Senate recede from Senate amendments & amends to include .01003.

**Rep Adams:** Second.

**Chairman Kasper:** Further discussions?

**Roll call was taken on HB 1382 for the Senate to recede from Senate amendments & amend as follows to adopt .01003.**

**Chairman Kasper is the carrier for the House and Senator H Anderson is the carrier for the Senate.**

DF 4/12/19

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1382

That the Senate recede from its amendments as printed on pages 1395 and 1396 of the House Journal and page 1116 of the Senate Journal and that House Bill No. 1382 be amended as follows:

Page 1, line 2, after "services" insert "; and to provide an effective date"

Page 1, line 6, after "**consent**" insert "**- Refund**"

Page 1, after line 6, insert:

"1."

Page 1, line 8, replace the second "the" with ":

a. The"

Page 1, line 9, after "representative" insert: "; or

b. The pharmacy provides the patient with notice of the upcoming delivery through more than one communication attempt, by different means, and the patient or the patient's authorized representative does not respond indicating the patient does not want the refill.

2. If a pharmacy delivers a refill in violation of subsection 1:

a. Within thirty days of the patient's or the patient's authorized representative's notification of the pharmacy of the unwanted refill, the pharmacy shall refund all payments received by the pharmacy relating to the unwanted refill.

b. Within thirty days of the pharmacy's, patient's, or patient's authorized representative's notification of the health plan or the pharmacy benefits manager of the unwanted refill, the health plan and pharmacy benefits manager shall refund all payments received relating to the unwanted refill"

Page 1, after line 9, insert:

"SECTION 2. EFFECTIVE DATE. This Act becomes effective January 1, 2020."

Renumber accordingly

Date: 4/12/2019

Roll Call Vote: 1

2019 HOUSE CONFERENCE COMMITTEE  
ROLL CALL VOTES

BILL/RESOLUTION NO. HB 1382 as (re) engrossed

House Industry, Business & Labor Committee

- Action Taken
- HOUSE accede to Senate Amendments
  - HOUSE accede to Senate Amendments and further amend
  - SENATE recede from Senate amendments
  - SENATE recede from Senate amendments and amend as follows
  - Unable to agree, recommends that the committee be discharged and a new committee be appointed

Motion Made by: Rep Lefor Seconded by: Rep Adams

Representatives	4/8	4/10	4/12	Yes	No	Senators	4/8	4/10	4/12	Yes	No
Chairman Kasper	X	X	X	X		Sen H Anderson	X	X	X	X	
Rep Lefor	X	X	X	X		Sen Clemens	X	X	X	X	
Rep Adams	X	X	X	X		Sen Hogan	X	X	X	X	
Total Rep. Vote						Total Senate Vote					

Vote Count Yes: 6 No: 0 Absent: 0

House Carrier Chairman Kasper Senate Carrier Sen H Anderson

LC Number 19.0959 . 01003 of amendment

LC Number . 03000 of engrossment

Emergency clause added or deleted

Statement of purpose of amendment

Adopt amendment .01003

Insert LC: 19.0959.01003  
House Carrier: Kasper  
Senate Carrier: Anderson

### REPORT OF CONFERENCE COMMITTEE

**HB 1382:** Your conference committee (Sens. Anderson, Clemens, Hogan and Reps. Kasper, Lefor, Adams) recommends that the **SENATE RECEDE** from the Senate amendments as printed on HJ pages 1395-1396, adopt amendments as follows, and place HB 1382 on the Seventh order:

That the Senate recede from its amendments as printed on pages 1395 and 1396 of the House Journal and page 1116 of the Senate Journal and that House Bill No. 1382 be amended as follows:

Page 1, line 2, after "services" insert "; and to provide an effective date"

Page 1, line 6, after "consent" insert "- Refund"

Page 1, after line 6, insert:

"1."

Page 1, line 8, replace the second "the" with ":

a. The"

Page 1, line 9, after "representative" insert: "; or

b. The pharmacy provides the patient with notice of the upcoming delivery through more than one communication attempt, by different means, and the patient or the patient's authorized representative does not respond indicating the patient does not want the refill.

2. If a pharmacy delivers a refill in violation of subsection 1:

a. Within thirty days of the patient's or the patient's authorized representative's notification of the pharmacy of the unwanted refill, the pharmacy shall refund all payments received by the pharmacy relating to the unwanted refill.

b. Within thirty days of the pharmacy's, patient's, or patient's authorized representative's notification of the health plan or the pharmacy benefits manager of the unwanted refill, the health plan and pharmacy benefits manager shall refund all payments received relating to the unwanted refill"

Page 1, after line 9, insert:

"**SECTION 2. EFFECTIVE DATE.** This Act becomes effective January 1, 2020."

Renumber accordingly

HB 1382 was placed on the Seventh order of business on the calendar.

**2019 TESTIMONY**

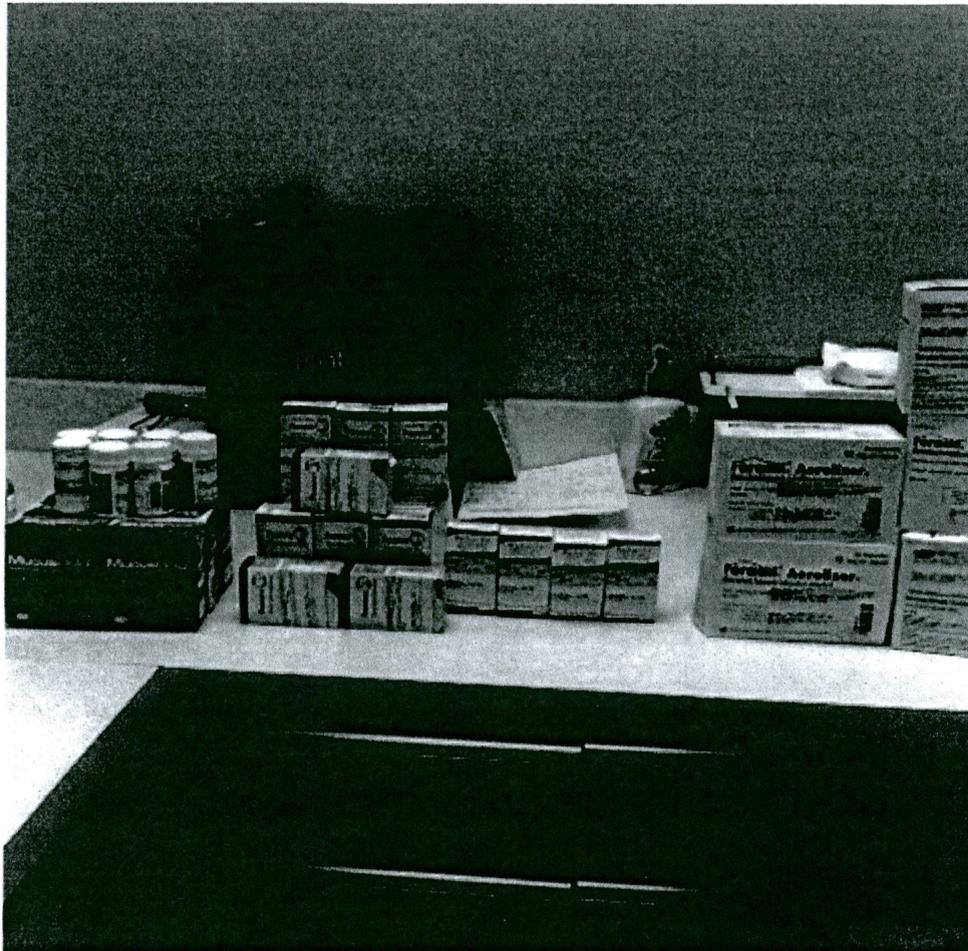
**HB 1382**

HB1382  
#1  
1.30.19



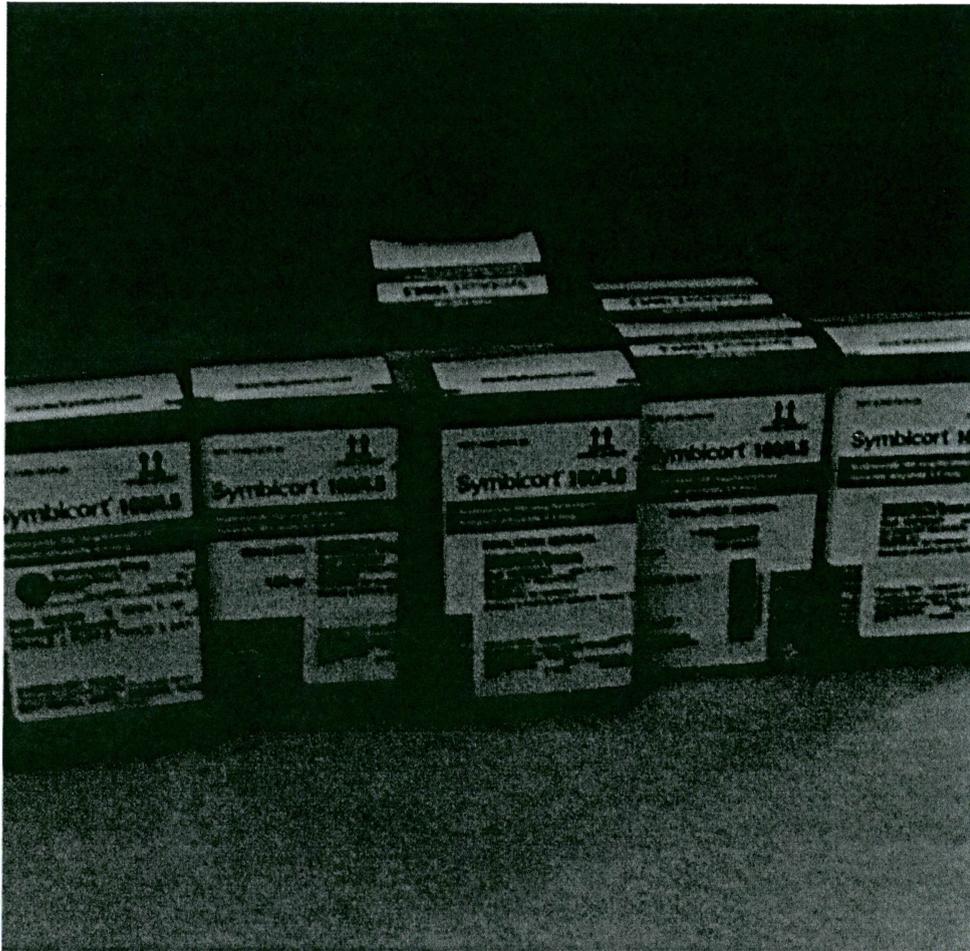
Unidentified pharmacy in central U.S. Patent brought to pharmacy after they tried cancelling 3 or 4 times.

HB 1382  
#1  
1.30.19



Dickinson - PBM mail order pharmacy  
for a VA patient. Patient brought  
them to the pharmacy's "Drug Take  
Back" bin.

HB 1382  
#1  
1.30.19



Carrington - mail order waste  
from PBM mail order pharmacy.  
Patient brought to the pharmacy's  
"Drug Take Back" bin.

HB 1382  
1.30.19  
#2



2900 Ames Crossing Road  
Eagan, Minnesota 55121

## Oppose House Bill 1382

House Industry, Business, and Labor Committee  
January 30, 2019

Submitted by LuGina Mendez-Harper, Pharm.D., R.Ph.  
Government Affairs Principal  
Prime Therapeutics

Chairman Keiser, Vice Chair Lefor, and Committee Members:

Thank you for the opportunity to submit testimony in opposition of House Bill 1382.

My name is LuGina Mendez-Harper and I am a pharmacist who works for Prime Therapeutics. I am currently working with our government affairs team but previously served as the Pharmacist-in-Charge for Prime's mail and specialty pharmacies. I also served the citizens of New Mexico for over 7 years through my service on the New Mexico Board of Pharmacy.

Prime Therapeutics is a pharmacy benefit manager (PBM) owned by 18 Blue Cross Blue Shield plans including Blue Cross Blue Shield of North Dakota. We improve member's lives by making the use of prescription drugs safer and more affordable.

We respectfully oppose House Bill 1382 because we are concerned about continuity of patient care and detrimental health outcomes if mail order and home delivery pharmacies are required to obtain patient consent prior to every refill. This is especially of concern for patients with complex diseases who are using specialty pharmacies.

Mail and home delivery are options used by both in-state and out-of-state pharmacies. Patients may use mail or home delivery for convenience, specialty medication management, or cost savings. Regardless of why mail or home delivery is chosen by patients, all pharmacies are required by law to obtain prescriptions before mailing or delivering medicines to patient's homes. This requires an active and engaged decision by the patient or prescriber in that a prescription must be submitted to the pharmacy.

HB 1382

Attachment 2  
1-30-19

Mail service pharmacy is used in partnership with local community pharmacies in that urgent medication needs such as antibiotics for an infection are obtained locally. Patients may choose to use mail service pharmacy services for receipt of their long-term medicines. Blue Cross Blue Shield of North Dakota does not have any mandatory mail programs.

This issue has been discussed at length with the North Dakota Board of Pharmacy. In all instances, the patient or their prescriber sent prescriptions to the mail service pharmacy. Upon receipt of a prescription order from a doctor, mail service pharmacies process the prescription, unless otherwise instructed, with the presumption the patient directed their prescriber to send the prescription to a mail service pharmacy.

Prime respectfully opposes House Bill 1382 because of concerns over unnecessary delays in drug therapy with the potential for significant damaging health outcomes. This concern is coupled with the fact that the use of mail or home delivery pharmacy services requires an active and engaged decision by patients and their health care providers by submitting prescriptions to these pharmacies.

Thank you for your time and consideration. I am more than happy to answer any questions you may have.

Wednesday, January 30, 2019

House Industry, Business & Labor Committee  
HB 1382

CHAIRMAN KEISER AND COMMITTEE MEMBERS:

My name is Jack McDonald. I'm appearing on behalf of America's Health Insurance Plans or, as it is commonly known, AHIP.

AHIP is opposed to HB 1382 in its present form but would be neutral if the proposed amendments listed below were adopted.

We believe that home delivery or mail order delivery of pharmacy products best serves the interests of the insured customers of our members' health insurance plans.

The amendments would make the process consistent with the Federal Trade Commission's Negative Option Rule which requires that the member get a notification prior to shipment prompting them to let the pharmacy know that they DO NOT WANT the refill. If they do not respond, the refill goes through.

Copies of the FTC provisions are attached for your information.

Thank you for your time and consideration. I'd be happy to answer any questions.

#### PROPOSED AMENDMENTS TO HB 1382

Page 1, line 8, delete "delivery of" and delete "prior"

Re-number accordingly

(OVER)



# FTC Will Keep Negative Option Rule In Its Current Form

July 25, 2014

TAGS: [Bureau of Consumer Protection](#) | [Consumer Protection](#) | [Advertising and Marketing](#)

The Federal Trade Commission has completed its review of the Negative Option Rule and will keep the Rule in its current form.

\* The "Trade Regulation Rule Concerning Use of Prenotification Negative Option Plans" requires sellers to clearly disclose the terms of any such negative option plan for the sale of goods before consumers subscribe. In such plans, consumers are notified of upcoming merchandise shipments and have a set period to decline the shipment. Sellers interpret a customer's silence, or failure to take an affirmative action, as acceptance of an offer.

## ELECTRONIC CODE OF FEDERAL REGULATIONS

e-CFR data is current as of December 20, 2018

Title 16 → Chapter I → Subchapter D → Part 425

Title 16: Commercial Practices

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### PART 425—USE OF PRENOTIFICATION NEGATIVE OPTION PLANS

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#### Contents

§425.1 The rule.

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↑ Back to Top

#### §425.1 The rule.

(a) In connection with the sale, offering for sale, or distribution of goods and merchandise in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, it is an unfair or deceptive act or practice, for a seller in connection with the use of any negative option plan to fail to comply with the following requirements:

(1) Promotional material shall clearly and conspicuously disclose the material terms of the plan, including:

\* (ii) A form, contained in or accompanying the announcement, clearly and conspicuously disclosing that the subscriber will receive the selection identified in the announcement unless he instructs the seller that he does not want the selection, designating a procedure by which the form may be used for the purpose of enabling the subscriber so to instruct the seller, and specifying either the return date or the mailing date.

PROPOSED AMENDMENTS  
2019

January 30,

HB 1382

CVS Health—

Page 1, line 8, remove “delivery of a” and insert “an auto”

Page 1, line 8 after refill insert “service” and remove “prior”

Page 1, line 9 after “representative” insert “prior to initiating the service”

The bill with the amendment would read:

If a pharmacy offers a prescription through home delivery or mail order delivery services, the pharmacy may not initiate ~~delivery of a~~ an auto-refill service unless the pharmacy obtains ~~prior~~ consent from the patient or the patient’s authorized representative prior to initiating the service.

Robert W. Harms, JD

The Harms Group

Box 895

Bismarck, ND 58502

ND Bar Lic. # 03666

701-471-0959

HB 1382  
3/18/19  
#1 pg.1



Unidentified pharmacy in central N.S. Patent brought to pharmacy after they tried cancelling 3 or 4 times.

HB 1382  
3/16/19  
#1 pg. 2



Dickinson - PBM mail order pharmacy  
for a VA patient. Patient brought  
them to the pharmacist's "Drug Take  
Back" bin.

HB 1382  
3/18/19  
#1 pg.3



Carrington - mail order waste  
from PBM mail order pharmacy.  
Patient brought to the pharmacy's  
"Drug Take Back" bin.

Statement of LuGina Mendez-Harper, Pharm.D., R.Ph.  
Government Affairs Principal  
Prime Therapeutics  
House Bill 1382  
Senate Human Services Committee  
March 18, 2019

HB 1382  
3/18/19  
#2 pg. 1

Chair Lee, Vice Chair Larsen, and Committee Members:

Thank you for the opportunity to submit written comments and speak with you today.

My name is Dr. LuGina Mendez-Harper. I am a pharmacist with Prime Therapeutics. I previously served as the Pharmacist-in-Charge for Prime's mail and specialty pharmacies and was the Director of or Regulatory Affairs team. I also served the citizens of New Mexico for over 7 years on the New Mexico Board of Pharmacy.

Prime Therapeutics is a pharmacy benefit manager (PBM) owned by 18 Blue Cross Blue Shield plans including Blue Cross Blue Shield of North Dakota. We improve member's lives by making the use of prescription drugs safer and more affordable.

I am here today to respectfully oppose House Bill 1382 because we are concerned about North Dakota citizens potentially not having their medicines when needed if there is a delay in obtaining their consent prior to delivering a refill of their medicine via home delivery or mail order delivery services. This requirement affects both in-state and out-of-state pharmacies.

All pharmacies are required by law to obtain prescriptions from patients or their health care providers before mailing or delivering prescription medicines. This requires an active and engaged decision by the patient or prescriber in that a prescription must be submitted to the pharmacy.

Patients may choose to use delivery or mail service pharmacy for convenience or cost savings. Mail service pharmacy is used in partnership with local community pharmacies. Blue Cross Blue Shield of North Dakota does not have mandatory mail programs.

In a previous hearing on this legislation, it was stated the goal of this legislation is to mirror requirements of the Centers for Medicare and Medicaid Services (CMS). This legislation is not consistent with CMS requirements.

In 2014, CMS required consent prior to shipping prescriptions that were **not personally initiated** by the patient or their authorized representative. In 2016, CMS allowed automatic delivery of new prescriptions and authorized refills if the patient opted into the program and had experience using mail-order or other automatic delivery programs. CMS further clarified this did not require an additional opt-in procedure for obtaining consent prior to participating

HB 1382  
3/18/19  
#2 pg. 2



in automatic delivery program if the patient confirmed annually their desire to continue using the program.

Prime respectfully opposes House Bill 1382 due to concerns about continuity of care and inconsistency with CMS requirements. We respectfully request a no vote on this legislation.

Thank you.

HB 1382  
3/18/19  
#3 Pg. 1

Monday, March 18, 2019

Senate Human Services Committee  
HB 1382

CHAIRMAN LEE AND COMMITTEE MEMBERS:

My name is Jack McDonald. I'm appearing on behalf of America's Health Insurance Plans or, as it is commonly known, AHIP.

AHIP is opposed to HB 1382 in its present form but would be neutral if the proposed amendments listed below were adopted.

We believe that home delivery or mail order delivery of pharmacy products best serves the interests of the insured customers of our members' health insurance plans.

The amendments would make the process consistent with the Federal Trade Commission's Negative Option Rule which requires that the member get a notification prior to shipment prompting them to let the pharmacy know that they DO NOT WANT the refill. If they do not respond, the refill goes through.

Copies of the FTC provisions are attached for your information.

Thank you for your time and consideration. I'd be happy to answer any questions.

#### PROPOSED AMENDMENTS TO HB 1382

Page 1, line 8, delete "delivery of" and delete "prior"

Renumber accordingly



# FTC Will Keep Negative Option Rule In Its Current Form

July 25, 2014

TAGS: [Bureau of Consumer Protection](#) | [Consumer Protection](#) | [Advertising and Marketing](#)

The Federal Trade Commission has completed its review of the Negative Option Rule and will keep the Rule in its current form.

The "Trade Regulation Rule Concerning Use of Prenotification Negative Option Plans" requires sellers to clearly disclose the terms of any such negative option plan for the sale of goods before consumers subscribe. In such plans, consumers are notified of upcoming merchandise shipments and have a set period to decline the shipment. Sellers interpret a customer's silence, or failure to take an affirmative action, as acceptance of an offer.

## ELECTRONIC CODE OF FEDERAL REGULATIONS

e-CFR data is current as of December 20, 2018

Title 16 → Chapter I → Subchapter D → Part 425

Title 16: Commercial Practices

### PART 425—USE OF PRENOTIFICATION NEGATIVE OPTION PLANS

#### Contents

§425.1 The rule.

[↑ Back to Top](#)

§425.1 The rule.

(a) In connection with the sale, offering for sale, or distribution of goods and merchandise in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, it is an unfair or deceptive act or practice, for a seller in connection with the use of any negative option plan to fail to comply with the following requirements:

(1) Promotional material shall clearly and conspicuously disclose the material terms of the plan, including:

(ii) A form, contained in or accompanying the announcement, clearly and conspicuously disclosing that the subscriber will receive the selection identified in the announcement unless he instructs the seller that he does not want the selection, designating a procedure by which the form may be used for the purpose of enabling the subscriber so to instruct the seller, and specifying either the return date or the mailing date.



HB 1382

3/18/19

#4 p.1

March 18, 2019

The Honorable Judy Lee  
Chair, Senate Committee on Human Services  
600 East Boulevard Avenue, Red River Room  
Bismarck, ND 58501

**RE: OPPOSE H.B. 1382, Mail order and home delivery – Prior consent**

Dear Chair Lee:

The Pharmaceutical Care Management Association is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans and operate mail-order and specialty pharmacies for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, and other programs.

PCMA opposes this proposal as it does not allow a home delivery of a refill "unless the pharmacy obtains prior consent from the patient." We have heard this is to make North Dakota law mirror what the Centers for Medicare and Medicaid Services (CMS) requires in Medicare Part D. However, this is not consistent with the CMS requirement, as CMS allows for exceptions to the consent requirement, HB 1382 does not. In a Call Letter in 2014, CMS wrote "Part D sponsors should require their network retail and mail order pharmacies to obtain patient consent to deliver a prescription, new or refill, prior to each delivery. **Such confirmation is unnecessary when the beneficiary personally initiates the refill or new prescription request.**"<sup>1</sup> [emphasis added].

North Dakota should not discourage the use of mail service pharmacy by placing hurdles in the way of its use, as H.B. 1382 proposes to do. One of the tools relied on by employers and health plans to help control drug spending is the use of mail service pharmacies. Prescription drug services by mail are less expensive and, often more convenient for patients than brick-and-mortar pharmacies. Mail service pharmacy has also been found to: (1) expand the use of more affordable generic drugs; (2) improve patient safety by utilizing dispensing tools 20x more accurate than human dispensing; and (3) enhance patient adherence to prescription regimes, including 24/7 access to pharmacist counseling. A 2014 study by Visante found that mail order will save consumers, employers and other payers nearly \$60 billion over the 10-year period of 2015-24 than if those same medications were dispensed at a brick-and-mortar pharmacy.

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<sup>1</sup> Amy K. Larrick, Acting Director, Medicare Drug Benefit and C & D Data Group, CMS "Reauthorization of Automatic Delivery Exception for 2015" (September 2014)



HB 1382  
3/18/19  
#4 pg. 2

For the reasons stated above, we respectfully request a no vote on this legislation.

Sincerely,

A handwritten signature in black ink, appearing to read "Lauren", written in a cursive style.

Lauren Rowley  
Vice President, State Affairs  
Pharmaceutical Care Management Association

HB 1382  
3/26/19  
#1 pg. 1

Draft Amendment Instructions for HB 1382

As Proposed by Robert W. Harms

Page 1, line 8, overstrike "not"

Page <sup>1</sup>2 line 8, replace "unless" with "if"

Page 1, line 8, after "unless" insert a colon

Page 1, line 8, after the colon insert

"a. the pharmacy obtains prior consent from the patient or the patient's authorized representative; or

b. after notice of a forthcoming delivery, the patient does not instruct the pharmacy that the patient does not want the refill."

Page 1, line 8, overstrike "unless the pharmacy obtains prior consent from"

Page 1, line 9, overstrike "the patient or the patient's authorized representative."

Apr 8, 2019

HB 1382

4-5-19

Mike Schwab

Attachment 1

Potential Amendment to HB 1382:

Mail order and home delivery.

A pharmacy that offers a prescription through home delivery or mail order delivery services may initiate delivery of a refill if:

- a. The pharmacy obtains prior consent from the patient or the patient's authorized representative for each renewal prescription or refill; or
- b. After notice of a forthcoming delivery for each renewal prescription or refill, the patient does not ~~inform the pharmacy the patient does not want the refill~~ respond to more than one attempt, by different means, to obtain consent prior to each mailing or delivery.

Apr 8, 2019

HB 1382

Attachment 2

Anderson, Jr., Howard C.

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**From:** Jack McDonald <jackmcdonald@wheelerwolf.com>  
**Sent:** Sunday, April 7, 2019 10:10 PM  
**To:** Harms, Robert; Kasper, Jim M.; Lefor, Mike; Adams, Mary K.; Anderson, Jr., Howard C.; Clemens, David; Hogan, Kathy L.  
**Cc:** McDonald, Jack  
**Subject:** RE: HB 1382....pharmacy mail order restrictions (Conference Committee members)

**CAUTION:** This email originated from an outside source. Do not click links or open attachments unless you know they are safe.

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Thanx Bob. I'm working on these bills at the office now and agree with your comments. I'll talk to Sen. Anderson in the morning. This first meeting will likely be for each side to see where the other stands, and how firm they are. I think Howard will stand with us. It was his amendment.

*Jack McDonald*

WHEELER WOLF LAW FIRM  
Box 1776  
Bismarck, ND 58502-1776  
Ph: 701-751-1776; Fx: 701-751-1777  
[jackmcdonald@wheelerwolf.com](mailto:jackmcdonald@wheelerwolf.com)

**From:** Harms, Robert [mailto:robert@harmsgroup.net]  
**Sent:** Sunday, April 7, 2019 9:36 PM  
**To:** Kasper, Jim M. <jkasper@nd.gov>; Lefor, Mike <mlefor@nd.gov>; mkadams@nd.gov; hcanderson@nd.gov; Clemens, David <dclemens@nd.gov>; Hogan, Kathy L. <khogan@nd.gov>  
**Cc:** Jack McDonald <jackmcdonald@wheelerwolf.com>  
**Subject:** HB 1382....pharmacy mail order restrictions (Conference Committee members)

Dear HB 1382 Conferees.....

We look forward to seeing you tomorrow regarding HB 1382---the pharmacy mail order bill, and helping to answer any questions or provide more information you might need. Mail order has been found to be very cost effective, reduces waste, increases patient drug utilization, improves patient health and provides consumer convenience. The Senate amendments essentially incorporate the FTC "negative option rule"....which gives the consumer the right to refuse shipment, after he/she gets notice of a proposed shipment.

CMS has also been implicated in HB 1382---it was purported as reflecting CMS policy as introduced. It does not. As drafted the bill required patient consent for every refill---(so, my 88 year old Mom, had to "consent" in advance to having her prescription filed by mail every time, month in, month out, year after year). The Senate amendments provided some flexibility for mail order consent.

As you convene the conference committee for HB 1382 tomorrow we point to two items:

1. Comments from Para #2 in the attached PCMA letter.....which states: *In a Call Letter in 2014, CMS wrote "Part D sponsors should require their network retail and mail order pharmacies to obtain patient*

Apr 8, 2019

HB 1382

Attachment 2

*consent to deliver a prescription, new or refill, prior to each delivery. Such confirmation is unnecessary when the beneficiary personally initiates the refill or new prescription request.*"<sup>[1]</sup>

2. New information from CMS from the attached announcement that just came out—April 1, 2019 states: *Specifically, starting in 2020, CMS will permit Part D sponsors to allow their network pharmacies to offer a voluntary auto-ship program (i.e., no affirmative consent prior to shipping or delivering each new or refill prescription) if accompanied by the following enrollee protections:*

- *Pharmacy requires enrollees to opt-in to auto-ship refills on a drug-by-drug basis after an initial fill and permits enrollees to opt-out of auto-ship refills anytime;*
- *Pharmacy provides a minimum of 2 shipping reminders before each auto-shipped refill;*

and

- *Pharmacy provides a refund for any unwanted fills. This applies to both new prescriptions ordered by the prescriber (consistent with the December 12, 2013 memo) and auto-shipped refills. (see p. 230)*

We will be around tomorrow and happy to answer any questions you may have. We of course would like to see the bill concurred as amended.

Regards,

Robert W. Harms, JD

The Harms Group

Box 895

Bismarck, ND 58502

ND Bar Lic. # 03666

701-471-0959

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<sup>[1]</sup> Amy K. Larrick, Acting Director, Medicare Drug Benefit and C & D Data Group, CMS "Reauthorization of Automatic Delivery Exception for 2015" (September 2014)

Apr 16, 2019

Attachment 1

**Proposed Amendment HB 1382**

A BILL for an Act to create and enact section 19-02.1-16.3 of the North Dakota Century Code, relating to pharmacy mail order and home delivery services.

**BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:**

**SECTION 1.** Section 19-02.1-16.3 of the North Dakota Century Code is created and enacted as follows:

**Mail order and home delivery - Prior consent.**

A pharmacy that offers a prescription through home delivery or mail order delivery services may initiate delivery of a refill if:

- a. The pharmacy obtains prior consent from the patient or the patient's authorized representative for each renewal prescription or refill; and
- b. The pharmacy requires enrollees to opt-in to auto-ship refills on a drug-by-drug basis after an initial fill and permits enrollees to opt-out of auto-ship refills anytime; and
- c. The pharmacy provides a minimum of 2 shipping reminders, by different means, before each auto-shipped refill; and
- d. The pharmacy provides a refund for any unwanted fills to the patient for their out of pocket costs and to the plan sponsor for the balance of the charges.

Apr 10, 2019

Attachment 2

19.0959.01002  
Title.

Prepared by the Legislative Council staff for  
Representative Lefor  
April 9, 2019

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1382

That the Senate recede from its amendments as printed on pages 1392 and 1393 of the House Journal and page 1116 of the Senate Journal and that House Bill No. 1382 be amended as follows:

Page 1, line 6, after "**consent**" insert "**- Refund**"

Page 1, after line 6, insert:

"1."

Page 1, line 8, replace the second "the" with ":

a. The"

Page 1, line 9, after "representative" insert: "; or

b. The pharmacy provides the patient with notice of the upcoming delivery through more than one communication attempt, by different means, and the patient or the patient's authorized representative does not respond indicating the patient does not want the refill.

2. If a patient or a patient's authorized representative notifies the pharmacy of receipt of a refill delivered under this section which the patient does not want:

a. The pharmacy may not charge the patient for the unwanted refill and within thirty days of the notification of the pharmacy, the pharmacy automatically shall refund to the patient all payments made by the patient relating to the unwanted refill, including a copayment.

b. The pharmacy may not charge the health plan for the unwanted refill and within thirty days of the notification of the pharmacy, the pharmacy automatically shall refund to the health plan all payments made by the health plan relating to the unwanted refill"

Renumber accordingly

Apr 12, 2019

Attachment 1

19.0959.01003  
Title.

Prepared by the Legislative Council staff for  
Representative Lefor  
April 10, 2019

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1382

That the Senate recede from its amendments as printed on pages 1395 and 1396 of the House Journal and page 1116 of the Senate Journal and that House Bill No. 1382 be amended as follows:

Page 1, line 2, after "services" insert "; and to provide an effective date"

Page 1, line 6, after "**consent**" insert "**- Refund**"

Page 1, after line 6, insert:

"1."

Page 1, line 8, replace the second "the" with ":

a. The"

Page 1, line 9, after "representative" insert: "; or

b. The pharmacy provides the patient with notice of the upcoming delivery through more than one communication attempt, by different means, and the patient or the patient's authorized representative does not respond indicating the patient does not want the refill.

2. If a pharmacy delivers a refill in violation of subsection 1:

a. Within thirty days of the patient or the patient's authorized representative notification of the pharmacy of the unwanted refill, the pharmacy shall refund all payments received by the pharmacy relating to the unwanted refill.

b. Within thirty days of the pharmacy, patient, or patient's authorized representative notification of the health plan or the pharmacy benefits manager of the unwanted refill, the health plan and pharmacy benefits manager shall refund all payments received relating to the unwanted refill"

Page 1, after line 9, insert:

**"SECTION 2. EFFECTIVE DATE.** This Act becomes effective January 1, 2020."

Renumber accordingly