2017 SENATE INDUSTRY, BUSINESS AND LABOR

SB 2301

2017 SENATE STANDING COMMITTEE MINUTES

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

SB 2301
1/31/2017
Job Number 27640

☐ Subcommittee
☐ Conference Committee

Committee Clerk Signature	Eva Liebelt

Explanation or reason for introduction of bill/resolution:

Relating to specialty pharmacy services

Minutes:

Attachments 1-12

Chairman Klein: Called the committee back to order.

Senator Anderson: Introduced the bill. Written testimony, see attachment #1. (:45-2:22)

Mike Schwab, Executive Vice President of the North Dakota Pharmacists Association: In support. Written testimony, see attachment #2. (3:00-12:40)

John Olson, Representing the North Dakota Pharmacy Service Corporation for North Dakota: In support. I am going to provide some expertise from a nationally renowned lawyer. This testimony is addressed to the committee and the litigation summary that recites the most current litigation in the country involving Pharmacy Benefit Managers. Written testimony David A. Balto, see attachment #3 and Cases against Pharmacy Benefit Managers, attachment #4, (13:50-21:45)

Erik Christenson, PharmD and Chief Professional Officer at Heart of America Medical Center: In support. Written testimony, see attachment #5. (22:30-34:53)

Dan Churchhill, Pharmacist: In support. Written testimony, see attachment #6. (35:58-37:54)

Gary Boehler, Pharmacist Consultant for Dakota Drug, Inc.: In support. Written testimony, see attachment, #7. (38:25-49:30)

Chairman Klein: We will give the opposition 48 minutes.

Abigail Stoddard, Pharmacist for Prime Therapeutics: In opposition. Written testimony, see attachment #8. (50:00-58:24)

Senator Casper: You said the PBM's are the only thing left to help the employer pay for the drug and gave this 750,000-dollar example. What do you mean pay for the drug, you mean less expensive?

Abigail Stoddard: The employer or the insurance plan is paying for it. PBM's give them more options to help them afford it.

Senator Poolman: You give us this picture of this really extreme version of what a specialty drug is and you talked about how they are new. The pharmacists are telling us that you are adding specialty designations to drugs they have been prescribing since the seventies, very basic prescriptions. What is the criteria for getting on a specialty list? I don't know how getting it through the mail could be better than my local pharmacist.

Abigail Stoddard: It terms of definition; I don't have a definition to offer you today. What I can tell you is that it is about two things, the characteristics of the drug and the characteristics of the patient and the disease they have.

Chairman Klein: This isn't denying the pharmacy benefit group to continue doing business it is to more clearly create some transparency and understanding what a specialty drug is. Is this going to stop you from doing business?

Abigail Stoddard: The sponsor of this bill is trying to keep it to a minimum. We have to contract with all of these pharmacies in North Dakota.

Robert Harms, Lobbyist for CVS Health: In opposition.

Emily McGann, Regional Director for State Government Affairs for CVS Health: In opposition. Graph, Attachment, #9. She said that Abigail Stoddard touched on most of their major concerns.

Pat Ward, Lobbyist for Express Scripts: Written testimony, see attachment #10 and Handouts, The Anti-Competitive Effects of "Any Willing Provider Laws", Exhibit A, Visante, Exhibit B, Specialty Pharmacy and Networks, Exhibit C and Pharm Freedom of Choice fiscal note, Exhibit D, see attachment #11-A, B, C & D. (1:10:32-1:18)

Senator Casper: What has happened now is you have a pharmacist out there in a regular pharmacy and they get supplied the drug by the PBM but the PBM is getting paid by the insurance company and essentially the PBM is saying to the pharmacist, there are certain drugs you can provide and certain drugs you can't because you don't have the expertise level to provide those drugs.

Pat Ward: I think you would be better off asking some other people that know about the internal operations. The PBM doesn't provide the drugs the local pharmacy obtains the drug through wholesalers. The is a whole chain on how the drugs get from a drug manufacturer to the drug wholesalers. Most pharmacies belong to some kind of a purchasing group. What the PBM's do, they are Pharmacy Benefit Managers and they negotiate the deals with the drug companies and they also set up pharmacy networks. The local pharmacist becomes part of these pharmacy networks.

Pat Ward: Said that you don't hear customers complaining.

Chairman Klein: I can vouch that there are customers and they have written to me.

Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy: Neutral Testimony. Written testimony, see attachment #12. (1:30-1:32)

Chairman Klein: Closed the hearing.

2017 SENATE STANDING COMMITTEE MINUTES

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

SB 2301
1/31/2017
Job Number 27641

☐ Subcommittee
☐ Conference Committee

Committee Clerk Signature	Eva Liebelt

Explanation or reason for introduction of bill/resolution:

Relating to specialty pharmacy services

Minutes:

Attachment 1&2

Chairman Klein: Please come up to the podium.

Danielle McDermott, Pharmacy Technician at Heart of America Medical Center: In support. Written testimony, see attachment #1. (:08-4:28)

Chairman Klein: Glad you came in.

Tallie Schneider: In support. Written testimony, see attachment #2.

Chairman Klein: Closed the hearing.

2017 SENATE STANDING COMMITTEE MINUTES

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

SB 2301
2/7/2017
Job Number 28002

☐ Subcommittee
☐ Conference Committee

Committee Clerk Signature	Eva Liebelt

Explanation or reason for introduction of bill/resolution:

Relating to specialty pharmacy services

Minutes:

Attachment 1

Chairman Klein: Called the committee back to order. Last week we heard 2301, that was the bill that deals with the specialty drugs. We had a lot of information and we heard the concerns from the pharmacy side and the concerns that all of a sudden popped up on that. He went over the amendment that was handed out, see attachment #1.

Senator Poolman: They don't have to renegotiate their contracts for this to take effect, if the agreements are already in affect?

Chairman Klein: That would be my understanding.

Mike Schwab, Executive Vice President of North Dakota Pharmacists Association: Yes, the application on that would be very similar to on 2258. The reason being is we often won't see a new contract or renewal. We will just see amendments or addendums to existing contracts. (1:41-2:09)

Chairman Klein: Closed the meeting.

Senator Poolman moved the amendment, 17.0928.02001.

Senator Casper seconded the motion.

Roll Call Vote: Yes-7 No-0 Absent-0

Senator Poolman moved a do pass as amended.

Senator Casper seconded the motion.

Roll Call Vote: Yes-7 No-0 Absent-0

Senator Poolman will carry the bill.

17.0928.02001
Title.03000

Adopted by the Industry, Business and Labor Committee
February 7, 2017

CM
2/7/17

PROPOSED AMENDMENTS TO SENATE BILL NO. 2301

Page 1, line 2, remove "and"

Page 1, line 2, after "penalty" insert "; and to provide for application"

Page 2, after line 11, insert:

"**SECTION 2. APPLICATION.** This Act applies to contracts and agreements in effect on and after the effective date of this Act."

Renumber accordingly

Date: 2/7/17
Roll Call Vote #: 1

2017 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. SB 2301

Senate Industry, Business and Labor Committee

☐ Subcommittee

Amendment LC# or Description: 17.0928.02001

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 Senator Poolman Seconded By Senator Casper

Senators	Yes	No	Senators	Yes	No
Chairman Klein	x		Senator Marcellais	x	
Vice Chairman Campbell	x				
Senator Roers	x				
Senator Burckhard	x				
Senator Casper	x				
Senator Poolman	x				

Total (Yes) 7 No 0

Absent 0

Floor Assignment ______

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

Date: 2/7/17
Roll Call Vote #: 2

2017 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. SB 2301

Senate Industry, Business and Labor Committee

☐ Subcommittee

Amendment LC# or Description: 17.0928.02001

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 Senator Poolman Seconded By Senator Casper

Senators	Yes	No	Senators	Yes	No
Chairman Klein	x		Senator Marcellais	x	
Vice Chairman Campbell	x				
Senator Roers	x				
Senator Burckhard	x				
Senator Casper	x				
Senator Poolman	x				

Total (Yes) 7 No 0

Absent 0

Floor Assignment Senator Poolman

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

REPORT OF STANDING COMMITTEE

SB 2301: Industry, Business and Labor Committee (Sen. Klein, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (7 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2301 was placed on the Sixth order on the calendar.

Page 1, line 2, remove "and"

Page 1, line 2, after "penalty" insert "; and to provide for application"

Page 2, after line 11, insert:

"**SECTION 2. APPLICATION.** This Act applies to contracts and agreements in effect on and after the effective date of this Act."

Renumber accordingly

2017 HOUSE INDUSTRY, BUSINESS AND LABOR

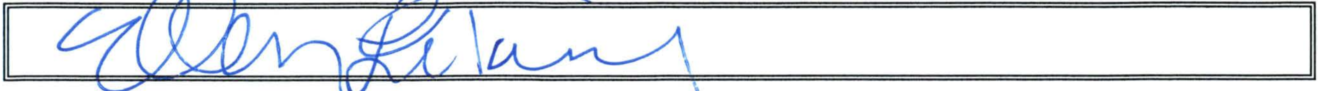
SB 2301

2017 HOUSE STANDING COMMITTEE MINUTES

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

SB 2301
3/20/2017
29505

☐ Subcommittee
☐ Conference Committee



Explanation or reason for introduction of bill/resolution:

Specialty pharmacy services.

Minutes: Attachment 1 – 19

Chairman Keiser: Opens the hearing of SB 2301.

Senator Anderson ~ District 8: Attachment 1.

Mike Schwab ~ Executive Vice President of the ND Pharmacists Association (NDPhA). Attachment 2.

15:45

Rep Lefor: How long have PBMs been around & what was the original intent of PBMs

Schwab: PBMs have been around since the 1970's. The big shift, they originally started out as claim processers between the pharmacy & the insurance company to check eligibility for patients. Around 1990, PBMs started to see a shift & that's when you saw advanced PCS merge with Care Mark. You also saw the emergence of MidCo & Express Scripts.

Rep Bosch: How many pharmacies are in the state of ND?

Schwab: There are 270 & that includes your hospital pharmacies, nuclear pharmacy, it included everybody.

Rep Bosch: How many have the status of the specialty designation?

Schwab: Basically, at this time we have the hospitals. We are hearing from the hospitals that they are now being asked to have dual accreditation. Retail side, only 2 businesses that are accredited.

Rep Becker: Can you go over subsections 2, 3, & 4 through the lens of a contract. My concern is the government stepping in & trying to modulate a contract between two private

entities. Does a PBM have a monopolistic type of advantage over this & any of these 3 types of cases? What is your argument for me that says that I'm not going to step in.? If you don't like the contract, then don't join.

Schwab: As far as the contractual relationship, it's take it or leave it contracts for the most part. We have multiple emails of examples. If you don't play with that player, you don't get to serve 75-80% of the patients that have coverage in this state. As far as the monopolistic, I guess when 3 PBMs own 80% of the market they have various market power. They say these are mandates upon them & we see it as removing mandates that were pushed upon us that are at the time definitely unnecessary.

Rep Kasper: The accreditation required by the PBM compared to the training & education that a pharmacist receives when they graduate from a college of pharmacy. How advanced beyond the college of pharmacy degree is this accreditation requirement?

Schwab: We have 300 pharmacists already authorized the immunizations. When you look at the specialty drugs being self-injectable drugs, they are qualified to provide that service.

Rep Kasper: The concern that the PBMs express with their additional accreditation, centers around the fact that the specialty drugs are injectable & they are attempting to say that the pharmacists are not qualified to do that?

Schwab: A lot of these drugs are self-injectables. The PBM will say they want a high quality network & service. We provide a lot of services too. If it comes down to reporting requirements, let's work collaboratively on trying to capture what you are not already able to capture through that data. One point that I would like to make is when we are looking at these high quality networks, on one hand they are requiring the pharmacies to go through a bunch of hoops but on the other hand, all 3 of the large PBMs oppose the board of pharmacy rule last year that required mandated counseling through mail order services.

Rep Kasper: On the high degree of service, the PBMs contention is that their customer service person on the telephone can give a better high degree of service than the pharmacists can face to face?

Schwab: I would ask you to ask that question to the PBMs. I would say yes.

Rep Kasper: Their service level for PBMs is never face to face because the service centers are located out of state.

Schwab: For the most part that is correct.

Chairman Keiser: Are the specialty lists of the 3 PBMs identical?

Schwab: No.

Chairman Keiser: If a prescription is filled through a PBM mail order & it's a specialty drug, what exposure does the local pharmacist have when the patient comes in for a consult?

Schwab: The pharmacists will definitely help the patient with a consult, but what we run into an issue sometimes, is that we are not sure, was the medication stored properly, did it arrive properly & at the same time.

Chairman Keiser: Page 1, section 3, it prohibits PBM from owning or having ownership interest in the patient assistance program or mail order pharmacy unless agrees to fair competition. What is fair competition?

Schwab: I believed that would become a legal discussion.

Rep Becker: On lines 2 & 3, "& no interference with prospective economic advantage", I have no idea what that means?

Schwab: That would be providing misleading statements, misrepresentation or potential harm to the competitor.

Chairman Keiser: Is that defined anywhere in code or is that your interpretation?

Schwab: Maybe the next presenter can touch on that.

Rep Beadle: In subsection 2, where the PRM or third party payer needs to disclose to the employer any difference in the spread pricing. When the employers gets this information, unless they know what they are dealing with on that information would be worthless to them. It's creating paperwork to send out to the employer just for their knowledge. Why is this information necessary to get back to the employer & wouldn't there be any issues possibly with HIPAA or some security issue if the employer is going to figure out what their prescription is & the pricing difference?

Schwab: Data is exchanged daily. I believe HIPAA wouldn't be an issue at all. We would like the employer to make that decision. We have nothing to hide & we would be more than happy to disclose that.

29:30

John Olson ~ Representing David Balto-Law Offices of David Balto-Washington DC: Attachment 3 & 3A.

41:40

Rep Kasper: Are you also aware of the bills that have been introduced into the US congress that deals with the investigations of PBMs & the lack of transparency? Are you aware of what congress is looking at?

Olson: Yes, I am to some degree of legislation. Congress passed legislation several years ago regarding the disclosure of prices by the PBMs.

Rep Becker: You gave an example where Meridian dropped the contract, went through transparent PBM, paid 2 million dollars. Why that approach can't be used, that obviously the free market approach?

Olson: Meridian also has in house pharmacies where they could compare the cost. They were in a better position to investigate & make that determination.

Rep Becker: If you don't like the 3 big PBMs, why not go to the others that are more transparent?

Olson: These are contracts of adhesion; they involve large employer groups. The pharmacy is not going to sign a contract with a major PBM that has substantial consumer base, then they can't participate in that market. I'm not offended to address some of these problems by imposing legislative mandates on these PBMs. They are the only ones in the industry that don't have the kind of regulation we need to keep health care costs down. We are just one element in the entire health care industry that is not being regulated. The pharmacists, doctors, hospitals & everybody else is. It seems that the PBMs don't have the scrutiny & regulation that would produce more competitive prices & market.

Rep Becker: Page 2, lines 2 & 3, I have serious concerns with the fair competition. I don't know what that means except that it's job security for some lawyers to figure out.

Olson: If the committee is concerned, they can write a definition.

Chairman Keiser: Dennis is at LC getting answers to those questions.

47:00

Eric Christenson ~ PharmD & Chief Professional Officer at Heart of America Medical Center: Attachment 4.

59:00

Rep Kasper: How much negotiation is there & how often were you able to negotiate in the contract with the PBM that was different in what they presented to you.

Christenson: There are no negotiations. It's take it or leave it?

Rep Kasper: Does that include Prime Therapeutics but it also includes other PBMs that you deal with in ND?

Christenson: To my knowledge, I have never been able to negotiate a pricing or a pace inclusion issued within a PBM. All the contracts that I have worked with, is a take it or leave it agreement.

Rep Kasper: The accreditation requirement that the PBMs are now imposing on local pharmacists over dispensing the specialty drugs. Three questions, how does this

accreditation work, what is the cost, time & money to get accredited & what does it accomplish if you do choose to become accredited?

Christenson: What I saw is a lot of red tape which seems impossible for small independent pharmacies to carry out. If you come late after hours or an emergency, if you are 1 second late, you get fined. That doesn't make any sense. To get accredited you need thousand-hour contact time & proof that with the drug the company is selling. They are an insurance company, there is multiple steps. The accreditation cost more than the payback.

Rep Kasper: The list of specialty drugs, the list continues to increase, increase & increase. Now there are specialty drugs that called specialty drugs that ridiculous to be called specialty drugs but they are being called that by the PBMs. Can you talk about that?

Christenson: To begin with, that a nebulous list. I've never seen the list. It's more expensive to be a specialty list to make money.

Rep Bosch: The loophole & jumping through hoops, are there any requirements of the specialty pharmacist that do make sense & is there a difference between any pharmacist of the 270 that we have?

Christenson: No two professionals are the same. I do believe that is the job of the state governing board to determine what that is. They are our direct competition & they are accrediting us.

Rep Dobervich: Patient care & access, would your pharmacy be able to get the specialty drug if they happen to be in the hospital & they are on drugs. It happens to be their monthly injection date; the specialty drug is usually delivered to their home. They need their drug. Would your pharmacy be able to get that medication so the patient could have it in the hospital? Would the patient have to call the specialty pharmacy & have it delivered it to them?

Christenson: The PBMs do sometimes allow a one-time dispense. The problem is getting paid & reimbursed.

Chairman Keiser: The liability side, a prescription come & it freezes, you provide a consult. Isn't that a significant liability? You provided the consolation.

Christenson: Absolutely, I tell them I can't verify it.

1:11:15

David Olig ~ Pharmacist & Pharmacy Owner from Fargo: Attachment 5.

1:30:30

Rep Kasper: Have you ever been able to negotiate a contract with a PBM?

Olig: No, they don't even respond.

Patric Branko ~ CEO at Heart of America Medical Center in Rugby: Attachment 6.

1:40:00

Dustin Hager ~ Physician Assistant at Heart of America Medical Center in Rugby: Attachment 7.

1:47:30

Tallie Schneider ~ Constituent: Attachment 8.

1:54:00

Chairman Keiser: When you were trained, where you not trained on these "specialty drugs"?

Schneider: Yes, we learned about all of these medications in school. There is medication that wasn't specialty but is now considered specialty. Cost seems to be a big thing driving that?

Rep Boschee: Can you think of any other situation where you as a pharmacist & also a patient, would not have been able to receive the care or medicine where the PBM is dictating that you can't do that.

Schneider: Yes, I've seen it with insulin patients as well.

Gary Boehler ~ Pharmacist Consultant-Dakota Drug, Inc: Attachment 9.

2:04:20

Dan Churchill ~ Represent Mitchell Page & self: Attachment 10

Rep Kasper: Have you had the opportunity to negotiate?

Churchill: Essentially no.

2:06:00

Jerry Jurena ~ President of ND Hospital Association: Attachment 11.

2:07:05

Mark Hardy ~ PharmD-Executive Director of ND State Board of Pharmacy: Submitted attachment 12.

Tim Stiner ~ Constituent: Submitted attachment 13.

Chairman Keiser: Reopens the hearing on SB 2301. Anyone here to testify in opposition to SB 2301?

Abby Stoddard ~ Pharmacist for Prime Therapeutics: Attachment 14.

2:17:45

Rep Kasper: You said that it's going to cost BCBS consumers $500,000, can you tell us how that will happen?

Stoddard: This will take the accreditation requirement that they currently have in order to participate in the specialty network. Basically makes the specialty network akin to your 2015 law that says that everyone with a ND pharmacy license has to be allowed to participate. That accreditation is good for the quality of our members but it's also a way for us to narrow the field. When we require accreditation, I narrow the field & those providers compete both on quality & on price.

Rep Kasper: I was under the impression that the prices that local pharmacist received for the drug & the price that the mail order are set by the PBM? Is that not correct?

Stoddard: We set the prices for mail order contracts for our own facilities. The prices we pay other pharmacies, that is up to the PSAO to the chain pharmacy as to what is negotiated in their individual contracts.

Rep Kasper: We've heard testimony that pharmacists have to sign your contract & it's mostly take it or leave it with no negotiations. You factor the contract terms up front & you are paying what you wish to pay the price to the pharmacist. They don't get to say our price is here & you are paying us here, it's the other way around, isn't it?

Stoddard: I think we disagree on that. I would actually look to your 2015 law to see what you are describing.

Rep Kasper: I asking you what you do in practice. You are representing Prime Therapeutics, is that correct? The contract that is negotiated by you, your PBM, we heard it's a take it or leave it contract. You present the contract, take it or leave it or you are out of your network. In the contract because it's generally take it or leave it, you're setting the pricing & in the reimbursement of the drugs that are being prescribed, you are set the reimbursement level based on your schedule. Is that correct?

Stoddard: In ND, you have a "any willing provider" law that says that anyone is allowed to participate as long as they accept our terms & conditions. I believe the situation you are describing is an unintended consequence of that law. It says that the only contracts, all the PBM has to do is set out their terms & conditions for others to agree to. In other states where we do not have that law, negotiations can go up & down.

Rep Kasper: You set the pricing, not the pharmacy?

Stoddard: That's correct.

Rep Kasper: Do Prime Therapeutics receive rebates from the drug manufacturers?

Stoddard: I want to limit the discussion on rebates for this bill. I can tell you about rebates, but this bill doesn't have anything to do with manufacturer rebates from pharmaceutical companies.

Chairman Keiser: You can say, "I refuse to answer it", but we can subpoena the information if we need to but we won't.

Stoddard: What I will answer on rebates is that in general is a way we provide employer group savings. Manufacturers set list prices for drugs, we don't set those list prices, the manufacturers do. Then PBMs negotiate with those manufacturers for deeper discounts. Those discounts again as Prime is owned by Blue Cross go 100% to BCBS & to their employer/client that they serve. When it comes to specialty drugs. These drugs have monopolies in the categories that they serve.

If there is someone out there to be able to negotiate a rebate from a pharmaceutical manufacturer on life savings specialty cancer medication, I would love to hear from them.

For the drugs within this scope of this bill, rebates are not a factor & they are not a factor in this legislation as written either.

Rep Kasper: I think you said yes you do receive rebates.

Stoddard: I said that we receive rebates that are passed through to Blue Cross & their employer clients.

2:23:45

Rep Kasper: Are you stating, all the rebates, 100% you are passing the rebates through to the employers, so they are enjoying the savings or are some of the rebates going to some other place?

Stoddard: It's negotiated in the terms of the contract for their relationship. All of our contracts have auditing clauses., If an employer group at any point feels that they are not getting what they have signed up for in their contract, they will audit us. There is an entire industry of consultants that do exactly that. If they find out they are not getting what they think they paid for, they drop us & vote with their feet & move to a different provider.

Rep Kasper: So, you just stated that all of your PBM contracts with the employers in ND, allow that employer to audit PBMs if they desire?

Stoddard: Absolutely.

Rep Kasper: You talked about accreditation & you are saying that you wish to limit the amount of pharmacists in ND that can have access to your specialty list. You are saying that

55 of them are there now. We heard earlier that there is about 270 pharmacists. Are you implying that the other 220 pharmacists in ND are really not qualified with their education?

Stoddard: I'm not implying that they are not capable but they need to go through a separate accreditation outside the board of pharmacy. The license you get from the board of pharmacy is general state license. When it comes to specialty drugs, not all pharmacists are created equal. We need this extra layer of accreditation to ensure that that is handled properly.

2:26:45

Rep Kasper: You don't think the pharmacy board is doing their job because the other 220 pharmacists in our state, they are not actually accredited. Would you be willing to provide to the board of pharmacy your recommendation on how they should enhance their accreditations standards so the board of pharmacy can do the accreditations in the state of ND compared to the outside crediting organizations to help enhance their standards to the local pharmacies so they could meet those levels of accreditation?

Stoddard: We've heard from the board of pharmacy also & I'm not disagreeing with that avenue. I am disagreeing with SB 2301 where it says that we can't require any other accreditations. So we have the proponents saying accreditation is important & they are going to do the accreditations. We have us also saying that accreditation is important & somebody needs to be doing the accreditations but, SB 2301 says no one can require any additional accreditation. I would be willing to help them develop that, if that's an avenue they want to choose. Then that section would have to be removed from 2201.

Rep Kasper: List of specialty drugs that are increasing. Can you share with us your current list of specialty drugs PBMs say are specialty drugs?

Stoddard: It's publically available on Blue Cross' web site & it's our standard list of specialty drugs but again, what PBMs don't do, is absolutely control the benefits.

Rep Boschee: We have incidences where employers are negotiating, what & how their employees receive their pharmaceuticals. Is there any other way an employer is deciding how someone who has an insurance policy receiving the care?

Stoddard: Absolutely, I have the folks from Blue Cross who will come up. The employers are the ones who set the parameters of their benefits. The employer, the one who is paying the benefits, is in ultimate control of that benefit from a robust to a more narrow benefit.

Rep Bosch: The list, is there a list that is larger?

Stoddard: I believe this is as large as it gets in ND & it goes down from here.

Rep Kasper: The employer can decide what the benefits will be & what the pharmacy benefit will look like, you probably talking about a self-insured. A fully insured plan with Blue Cross, the employer can choose a plan, but that's all they can choose. Blue Cross determined all the rest of the benefits, pharmacy & employer in fact cannot ask to have a different PBM than on Prime Care Therapeutics on a fully insured plan. On the self-funded plan, I've never heard

Blue Cross tell me that if I didn't like to use Prime Care Therapeutics, that I could have Blue Cross choose someone else. I'm puzzled that the employer has so much choice.

Stoddard: For a fully insured employer, they will come to Blue Cross & work with a broker to determine how much they going to pay for that benefit. They will be given different options with Blue Cross. With Blue Cross, perhaps Prime would be only PBM on those off the shelf options. If they don't want to work with Prime, they certainly don't have to. For a self-insured, that group determines where those dollars go & what the benefit looks like.

2:33:30

Chairman Keiser: Does Prime Therapeutics have a mail order system?

Stoddard: Yes.

Chairman Keiser: If a patient places a mail order, who do they talk to if they want a consult?

Stoddard: The mail order facility calls the patient saying we received an order from you. If we don't hear back, we will call again & tell them we received an order from the doctor for you. If you want to talk to us call us back. For Blue Cross for expedient care, some of the employee benefits have set up if the drug cost is $25, we can ship it to them & Blue Cross will handle the bill. We they receive that medication; it comes with all of the 800 numbers to call Prime Therapeutics 24/7 & all the paper instructions.

Chairman Keiser: If I call, who do I talk to?

Stoddard: You will talk to a representative & they would ask you what your question is & then they do a triage that questions to a pharmacist.

Chairman Keiser: If I do talk to a pharmacist in Prime Therapeutics, do your pharmacists have any different training than our pharmacists in this state?

Stoddard: We have a traditional mail order facility & those pharmacists may not have different training or specialty pharmacy training facility. Those pharmacies will have different training.

Chairman Keiser: What will be different for ours trained at NDSU?

Stoddard: Those pharmacies will be in our accredited facilities & other facilities in ND, they will require 1 accreditation. For our facility, we have duel accreditation, they will have hours & hours of training on just those subset of specialty drugs. That is the additional expertise that they will provide.

Chairman Keiser: Do you have a requirement that a pharmacy starts a service that they would have toanswer within a certain period of time or they would be fined a thousand dollars? Do you have that requirement?

Stoddard: No, what I believe the proponents meant was that was a requirement of the accrediting body. They will get accredited & that is a requirement of accrediting body. If they don't meet those metrics, they will be penalized. We don't make someone use one specific accrediting body. It's not a requirement of Blue Cross or Prime.

Rep Becker: You said that 90% of drugs will be specialty drugs by 2020. 90% of what?

Stoddard: Nine of the 10 of the top selling drugs will be specialty drugs by 2020. They will be top selling drugs by revenue because they are so costly.

Rep Kasper: You indicated that your specialty pharmacists are in your call center are all accredited. What accreditation they have received. Can you provide us the name of the accrediting organizations & can you assure us that 100% of those pharmacists are accredited?

Stoddard: It's semantics, the facilities they work in are accredited & the facilities have training requirements. Our facilities are URAC & NCQA accredited. There are training protocols for specialty drugs that everybody facilities go through.

Rep Kasper: You are not saying that all the pharmacists there have some type of accreditation like you want the ND pharmacists to receive. You are saying that the facility which doesn't give any advice what so ever. Is that correct.

Stoddard: No, we are asking the pharmacies in ND go through additional accreditation. With our facilities we have a non-resident pharmacy license in ND & we receive additional accreditation. I think you are getting confused, there is pharmacy & pharmacists. Everything in this bill & what we are asking is for accreditation on facility.

Rep Kasper: How do one receive this facility accreditation?

Stoddard: There are several independent bodies that you can go to & find an application process for those bodies. It requires a lot of time, effort & those independent bodies, they will charge for those service. We have pharmacies in ND that agree to that. When you hear from the proponents, that is not what they want to do.

Rep Kasper: The accreditation, you indicated that the pharmacists in your call center have certain training that makes them more qualified to provide advice on specialty drugs than the ND pharmacists who have their pharmacy from the NDSU, what special training are those pharmacists in your call center receiving that our local pharmacists have not already received or could not receive?

Stoddard: The types of training that employees of an accredited facility will receive is dictated by that accrediting body.

Pat Ward ~ Representing Express Scripts (ESI): Attachment 15.

2:45:20

Andy Behm ~ Representing Express Scripts: Attachment 16

3:00:30

Rep Kasper: You indicated that you have 75 specialists on this one protocol in your office, how many customers do they serve nationwide?

Behm: I'm not sure the exact number or individual clients. I believe it might be the neighborhood of 1,500 to 2,000. I know the number I've heard is 450,000 patients total that are serviced.

Rep Kasper: You have indicated that you have a specialty drug network of independent group that determines what specialty drug? Are you able to provide the committee names & credentials of this committee or that proprietary?

Behm: I would be happy to provide the list of name & credentials.

Rep Kasper: Your testimony & others before you seem to imply that the employers are quite sophisticated in knowing the intricacies of health insurance & PBMs. I would grant that the larger employers maybe, but in the business I'm in, working in the area of health care & insurance, I can assure you that employers don't know anything about this. Are you implying that even though smaller groups have an understanding of what you are talking about on how PBMs work?

Behm: What I'm saying is that those smaller employees have the ability to determine what they want their benefits to be. I can't speak to their level of knowledge. You have the decision making ability to determine how you want to set your benefit up.

I'm somewhat familiar with the implementation process & how they work with clients. It's not, "here's the contract & we have everything taken care of". There are very complex check lists that we go through with clients for autonomy & they get to make benefit decisions. Those include our suite of standard products & services, they are complex.

I'm telling you absolutely, the autonomy & ability to make that decision resides with the employer or individual that is hiring us to provide the services.

Rep Kasper: Would you provide this check list to the committee you just discussed & information you discuss on how they can make those choices; I've never seen one.

Behm: Those are typical client benefit implementation set up documents, I'm not sure if it's something I can share or not.

Rep Dobervich: When a patient become a specialty patient, you are getting medication from 3 pharmacies. When you are going to the same local pharmacy & when there is a tweak to your medication, your local pharmacists sees that. When you get it from 3 different places, how do they know that? Isa it up to me the consumer to update you or is it the doctor? How does that work?

Behm: Express Scripts is uniquely positioned to be able to help coordinate care. You are not only in a position able to gain visibility to the specialty medicines, but you are able to see all other medicines that are being processed through PBM services.

When our pharmacists are dispensing medicines & having one on one conversations with individual patients, they are privy to the entire patient's profile. You might be receiving medicines from 2 or more pharmacies, through our unique view, we are able to aggregate that information & see all of those particular claims. This is a lot of one on one dialogue; we will see if there is a change in a patient's specialty medicine or a change in a non-specialty medicine that is within our system that highlights specific issues that would be of concern.

Rep Dobervich: In real time, it would pop up hypothetically?

Behm: As the specialties pharmacists, you have a full view of not only the specialty but the other non-specialty medicines that have been adjudicated under your benefits. The specialty pharmacy is able to see the changes in the biologic as well as other changes in other medicines. There are checks & balances.

Rep Bosch: I'm assuming if the list is bigger, the insurance premiums are lower when negotiating?

Behm: I'm not sure, each contract is individual.

Rep C Johnson: In home consultation with clients, who does that?

Behm: We have 550 in field nurses.

Rep C Johnson: The nurses are not registered pharmacists or they are trained in your special accreditation program?

Behm: The nurses are accredited.

Rep Lefor: How many are located in ND & where?

Behm: I don't have that specific figure but I will obtain it for you.

Chairman Keiser: Get that information for us & how many calls in the last 5 years.

Rep Kasper: It's more expensive for a nurse to travel for cost containment.

Chairman Keiser: I talked about what are the major issues in health care & that's the hand off that occurs in hospitals. I would agree that you would have access to all the information of what drugs a person is using. Where the problems frequently on the handoff, the specialists that comes in may prescript a reasonable prescription, except when you go back in the file, it says that this person had an allergic reaction. How do you pick that up?

Behm: We have full view to the entire suite to the adjudicated medicines, so we have that at our disposals. There is the consultation that goes on with the individual patient, if there

are any red flags, there is connection with the prescribing physician. Based on the outreach, they close some of those gaps.

Chairman Keiser: Continues the hearing on SB 2310.

3:17:20

Robert Harms ~ Lobbyist for CVS Health: Introduces Julie Hagen.

Julie Hagen ~ CVS Caremark: Health plans are my clients. A client comes to me with a request for proposals. We need to respond to the criteria that they are going to be looking for in a vendor which is gathered & weighed.

My responsibility is to sign the contract & negotiate the pricing with the health plan as well as moving forward the relationship of the plan.

Performance guarantees are now in contracts. There are penalties attached to that. We do also have a specialty list posted on site, as well, as determining with the health plan. We sit down & discuss what is specialty drugs. We have teams that are led by pharmacists in place. We have a system in place & that's what triggers the exhaustion date. Explains CVS's process for clients.

3:24:30

Rep Bosch: When you talked the delivery of the local pharmacists & the mail order. Is there something that the mail order pharmacists do better than a local pharmacist on delivery?

Hagen: I imagine that the local pharmacists wouldn't be shipping the product. They would walk in & see the pharmacists face to face rather than a relationship.

Rep Kasper: Local pharmacies are not allowed to have a 90 fill. What is your policy on 90-day prescription fills with your mail order pharmacy compared to the local pharmacy?

Hagen: In our CVS world we have different channels. We have retail, mail & specialty mail. I am representing specialty mail. I'm referring to specialty mail; we do not dispense 90-days' worth of product.

Rep Kasper: Are there 30, 60 or one-time situations?

Hagen: For specialty pharmacy, it's usually a 30-day supply but if they are going out of US, more.

Rep Kasper: On any specialty fill, do you have a different co-pay requirement of a local pharmacist compared to your mail order pharmacists?

Hagen: My answer is no.

Rep Kasper: You indicated negotiating contracts, does you PBMs representatives go out & meet with employer groups who negotiate or done in a different way?

Hagen: We have a PBM salesforce that does meet with employers.

Rep Kasper: They would be self-insured plans?

Hagen: Mostly.

Rep Kasper: Do you have fiduciary liability on what you do as far as filling prescriptions or do you avoid fiduciary liability situation with your prescription fill?

Hagen: I'm not 100% sure in answering that.

Andy Peterson ~ Greater ND Commerce: Attachment 17.

3:32:35

Rep Kasper: You are not a pharmacist?

Peterson: No, I am not.

Rep Kasper: Did you listen this morning from pharmacists that indication that there is really no negotiation on the PBM contracts that are a take it or leave it. If that is a fact, would you say that is anti-competition.

Peterson: If that is in fact a fact, then there is some other discussion to have.

Rep Kasper: You say it might be anti-competition or you don't want to answer?

Peterson: I want to be careful in coming to a conclusion. I am putting you off.

Rep Kasper: I gave you the options if this is in fact a fact?

Chairman Keiser: Anyone else here to testify in opposition, neutral position of SB 2301. Closes the hearing.

Testimony for the record handed in but did not testify.

Mike Potts ~ Vice President of Health Innovation & Practice Transformation at BCBS of ND: Attachment 18.

Chairman Keiser: Closes the hearing on SB 2301.

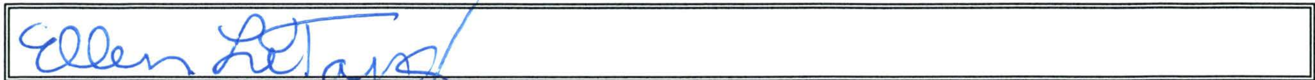
Blair Thoreson ~ Representing Pharmaceutical Care Management Association: Attachment 19. Did not testify.

2017 HOUSE STANDING COMMITTEE MINUTES

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

SB 2301
3/22/2017
29543

☐ Subcommittee
☐ Conference Committee



Explanation or reason for introduction of bill/resolution:

Minutes: Attachment 1

Chairman Keiser: Opens the hearing of SB 2301.

Chairman Keiser: Attachment 1.

John Olson ~ Represents Pharmacy Services Corp: Black's Law Dictionary. There is a definition of what is fair & advantage.

Rep Becker: All these words have a definition. What concerns me, do we know how to interpret aspects of a contract or behavior whether they call it in the parameter of the definition of the words.

My concern, when it becomes law, is how can we interpret whether someone has broken the law, what constitutes in a contract or behavior of the business, if they are not having fair competition?

Olson: When we get into situations where lawyers argue in court, they pull in those definitions & try to apply them to the facts that are presented. I can't tell you what a court will do because I don't know what facts go into a certain situations. I think self-dealing is one for me. Fair competition is a little bit more vague. The interference of prospective economic advantage, does have more vagary than the others do. Lawyers get involved in interpreting, discussing & applying those terms in various ways.

5:45

John Ward ~ Representing Express Scripts: I think Rep Becker is right on. One of our concerns is we have this language that is potential, unconstitutionally vague. This will be the situation that you will be in. Definitions don't mean anything to lawyers, what means something is precedence. That is only going to be developed through litigation. What

concerns us is not only will there be litigation challenging not only the constitutionality of the statute, but also the actual specific language that is involved with in it.

Rep Becker: How would a firewall be established according to subsection 3?

Ward: That's another area that doesn't mean anything to us. What are you talking about a firewall, it's very open ended & subject to interpretation.

Jack McDonald ~ Representing Prime Therapeutic: You also have to remember, you are making it a misdemeanor, a crime. You have to be very precise if you are being charged with committing a crime.

Bob Harms ~ CVS Health: My 2 concerns are the firewall & the firewall in regards to the contract. CVS has inside the corporation, a PBM which is CARE MART.

CARE MART applies its rules to every one of the clients that we serve including CVS drugstores. There is a firewall between the PBM & the retailers that the company owns.

Rep Kasper: Would you define firewall for your organization?

Harms: There is a division between the 2 corporate structure. I don't know the corporate bylaws. We have complaints about how the PBM's in the same company manages & adjudicates the claims. The PBM treats the CVS retailer the same as any other retailer in ND.

Rep Kasper: Would you state that what a firewall means is the one entity will not share within the other entity? Would that describe what a firewall in better terms.

Harms: I just don't know & can't speculate.

Rep Kasper: I'm just asking the firewall. I don't know.

Harms: The other concern, if a company in ND, they issue an RFP for their insurance plan. They talk to half dozen PBM's, including CVS Express Script Prime. That RFP says to the potential PMB; we want to look at your complete array of services. One of them has a mail order & a specialty component in side.

The entities should have the freedom to choose that service if they want to. This bill says that they can't do that.

Chairman Keiser: I'm not taking a position, I just wanted to know the definition.

Rep Becker: Move an amendment that ^remove subsection 3, lines 23-24-page 1 & lines 1-4-page 2.

Rep Beadle: Second.

Chairman Keiser: Further discussion?

Roll call on amendment with 4 yes, 8 no, 2 absent, motion failed.

Chairman Keiser: Is there further action?

Rep Louser: This subsection 3 where everybody focused. We have to find a better way to define what we are trying do as opposed to referencing something. I don't have that answer.

Rep Lefor: Wouldn't it be a good thing to do to talk to LC, look into this wording & adding the definitions into the bill?

Rep Becker: I agreed with the sense, if we are going to have terms that aren't defined in century code, it would be smart to define them. My concern is that the terms & phrases being used, we can define them in according to Black's Law, but determining them in what manner, it won't clear it up in the courts.

Rep Kasper: Looking at section 3, the intent is to say that the PBM can't share their information with other subsidiaries that do administrative functions in the mail order pharmacy shown on line 4.

The other words on line 2, fair competition, self-dealing & no interference with prospective economic advantage, that is superfluous to main point. If we are looking for words that mean something, if we would keep "fair competition & no self-dealing" but if we would consider amending out "& no interference with perspective economic advantage. After those words are struck, further "establishes a fire wall, which prohibits the sharing of information between the administrative function & the mail order pharmacy. That may define it better?

Chairman Keiser: I would like it to establish the firewall & take out the other stuff.

Further consider on page 2, line 2, the pharmacy benefits manager or a pharmacy benefits manager's affiliate or subsidiaries, may not own or have an ownership interest in the patient assistance program & a mail orders specialty pharmacy unless the pharmacy benefit manager affiliate or subsidiary. Then cut everything out. Also add, patience assistance program.

Rep Kasper: I think that I would support that.

Rep Becker: I was going to remove the Class B misdemeanor.

Rep Kasper: If that were taken out, what would be the penalty for violation of the contract?

Rep Becker: They would be forced to adhere to the terms of the contract, they wouldn't be facing jail time.

Rep Kasper: The problem I see, not having a penalty, we would continue to see what the PBM's have historically done for the last 15 or 20 years. We need some type of criminal action.

We have to have some type of criminal action involved or otherwise we will keep on getting what we always got.

Chairman Keiser: Further thought, food for thought. We will be back at 11:00.

Rep Louser: Are we comfortable with the definition of firewall?

Chairman Keiser: Let's ask Legislative Council.

2017 HOUSE STANDING COMMITTEE MINUTES

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

SB 2301
3/22/2017
29563

☐ Subcommittee
☐ Conference Committee

Ellen LeTang

Explanation or reason for introduction of bill/resolution:

Specialty pharmacy services.

Minutes: Attachment 1

Chairman Keiser: Opens the hearing of SB 2301.

Dennis Patroff ~ HIBL Law Intern: Attachment 1

Chairman Keiser: Any questions?

Rep Becker: Isn't firewall used in construction? So in place of firewall, have the definition.

Chairman Keiser: We will put the word firewall & put in the statement of firewall.

Rep Louser: I'm wondering what the committee's feeling on striking the words "no self-dealing".

Chairman Keiser: That is certainly open for discussion.

Rep Beadle: In regards to the definition of firewall. It precludes one person from sharing information with another person. I understand the intent but I see that as broadly generalized.

There will be some information shared in the hearing. I think our intent is to make sure it's not an unfair amount of information. Just saying, from sharing information with another might be problematic.

Rep Kasper: I believe the concern is solved with the last part of the amendment under section 3, where is says a firewall between an administrative function, mail order pharmacy & the patient assistant programs.

Rep Beadle: I understand that in theory, but we don't have a definition of patient assistant's programs in this bill. If they are going to operate & have a distribution entity, there is going

to have to be some sort of information shared in order to authorize that distribution or that mail order prescription being sent. You have to share some information.

Chairman Keiser: The term person means individuals or corporation. It is very broad.

Rep Kasper: Move that we take the suggestion of Rep Becker & remove the word "firewall" in section 3 of the amendment & substitute the words defining firewall. Page 1, after line 9 as well & put the definition down below.

Vice Chairman Sukut: Second.

Chairman Keiser: What you are proposing is to leave the lines 23-24, page 1 & continue mail orders, specialty pharmacy, unless the pharmacy benefits manager affiliate or subsidiary have a written policy that precludes one person from sharing information with another person. Is that what you are suggesting?

Rep Kasper: We take the definition & insert it in 3.

Chairman Keiser: Would you walk us through? Do we want to do anything on page 1 where we talk about the subject?

Rep Becker: I believe the proposed amendment, if we're to amend the amendment, we would say that all the changes on pages would be removed from that amendment. Then we would begin with page 2, line 2, & keep the amendment as it is before us in line 2, as well as line 3. At that point it would say "and establishes a written policy that precludes one person from sharing information with another person between the administrative function, the mail order pharmacy or assistant program".

Chairman Keiser: Everybody understand?

Rep Ruby: Can somebody explain the reason behind having this limitation of sharing of information? What justifies the name for it?

Chairman Keiser: Explains situation about an unfair playing field.

Rep Lefor: What we are doing it putting in written policy. So it says "establishes a written policy between the administrative functions, mail order pharmacy & patient assistance program". All we are requiring is in statute is that they have written policy? What is the provision if they violate their own policy?

Chairman Keiser: I hope we are putting more of the first part of Dennis' amendment.

Rep Beadle: I still think, if we don't clarify what we are talking about for information, there is going to be significant unintended consequences.

Chairman Keiser: I would suggest that we might want "personal health information"?

Rep Beadle: Identifiable information?

Rep Louser: I don't know why I feel that I'm stuck on the self-dealing. Are we looking at the issue being actually self-dealing or are we looking at sharing personal information? The issue we are trying to preclude from happening is actually self-dealing that we struck from this amendment.

Chairman Keiser: What is the definition of self-dealing? It's not in statute.

Rep Louser: The definition of self-dealing is much more self-evident than the definition of firewall was & could be.

Chairman Keiser: We did get the black definition.

Rep Lefor: If we go to page 2, line 2 & continue to have it "fair competition, no self-dealing & no interference with perspective economic advantage". Take out the word, "and establishes a firewall"?

Rep Ruby: I think the terms, "agrees to fair competition & perspective economic advantage" are pretty subjective terms. I'm not comfortable with those either.

On subsection 2, page 1, are we going to require them to disclose any difference if there's a difference of what was charged & what was paid? Aren't there administrative fees & all kinds of things? Is it for everyone, every drug, every script, every line item? They have to show that every week, every month, every year? That is an amazing amount of paperwork.

On subsection 2, that's subjective, how are you going to enforce it or proof it?

Rep Beadle: Reads the statute of self-dealing, 6-05.2-06 for financial dealing.

Chairman Keiser: If self-dealing is the issue, then we can make reference the banking section if it's appropriate or we can put it into the section. Are there any other sections the committee has concerns with?

Rep Ruby: It talks about the difference between what they charge? It seems every difference would be substantial.

Another concern is subsection 3.

Chairman Keiser: Subsection 2, "shall disclose to a plan sponsor", I think the intent is, if I'm a plan sponsor, that I have the to right to request that information.

Rep Kasper: That section refers to the spread pricing. If the PBM is spread pricing, they must disclose it. Most plan sponsors do not know that spread pricing occurs or the definition. This says it has to be disclosed to the plan sponsor which in most cases is the employer.

Rep Beadle: Because the definition of planned sponsor refers to 19-03.6, which is the pharmacy record audit section. That is correct in that.

My one comment in regards to this section, the intent is that the plan sponsor should have the ability to give that information. When we say we shall disclose, we don't tell them when or the timeline they have to disclose. I think then the plan sponsor shall have the right to request disclosure from the pharmacy benefits manager or third party payer of the price differential.

To flip the language around, so instead of "they shall disclose", say "this person shall have the right to disclose or audit". Flip it around so the action required would be on the plan sponsor to request it but there would be nothing from PBM that would be able to stop that.

Chairman Keiser: Committee members, any questions. It makes sense to me. That's our intent that the plan sponsor should be able to ask for & be provided that information. Obviously, the plan sponsor can vote with their feet.

Rep C Johnson: If we add on to the end "if or when requested by the plan sponsor".

Chairman Keiser: That would do it & clarify it. Would that work Rep Beadle?

There is still a motion before the committee.

Chairman Keiser: We have a motion before us to adopt the amendment distributed. Does the mover & second what to remove the motion or leave it?

Rep Kasper & Vice Chairman Sukut agree to remove the motion.

Chairman Keiser: We have the mover & the second agreeing to withdraw their motion. Do I have a motion?

Rep Beadle: Moves on page 1, subsection 2, add, "If requested by a plan sponsor contracted payer".

Rep Ruby: Second.

Chairman Keiser: Further discussion.

Voice vote ~ Motion carried.

Chairman Keiser: Reading the self-dealing for the bank, it doesn't work well for us.

Rep Beadle: I agree. The language will still be there if we wanted to adjust it to fit.

Chairman Keiser: The handout for John Olson, the Black Laws Dictionary, says that self-dealing is participation in a transaction that benefits oneself instead of another is owed a fiduciary duty. Does that cover it?

Rep Beadle: I believe that would cover the intent.

Chairman Keiser: If the committee wants, on starting on subsection 3, page 2, line 2, is to remove "agreed to fair competition, no self-dealing, & no interference with prospective economic advantages & establishes a firewall between", we could simply insert, the definition found to self-dealing. We can reference the Black's or put in the whole definition.

Rep Louser: So move.

Rep Bosch: Second.

Chairman Keiser: Further discussion?

Rep Ruby: I think it's a good amendment.

Voice vote ~ Motion carried.

31:40

Chairman Keiser: Anything else the committee would like to address?

Rep Becker: I move that we strike on page 2, lines 11 & 12.

Rep Beadle: Second.

Chairman Keiser: Further discussion?

Rep Becker: The purpose of my motion is there are a number of contracts that is understood that there is contract law & you can take it to court for action but it doesn't take it to criminal court automatically like this would. In another bill we have a Class B misdemeanor as the penalty.

The second reason is that there are some gray areas. I don't feel comfortable having a criminal penalty involving potential jail time.

Rep Kasper: I hope you resist the motion. We are given cases against pharmacy benefits managers. There are millions of dollars of civil actions that continues on. I think we need some type of penalty as well as the civil action because of the millions of dollars PBMs are making. They will continue doing it the way they are.

Rep Ruby: Who would be charged with that?

Rep Kasper: I would assume whoever has fiduciary responsibility for breached contract & action would be the person or persons charged.

Rep Becker: If there is a threat of a loss of billions of dollars, I don't know if a Class B misdemeanor which has $1,500 as the maximum penalty to find a fall guy that will be problematic with a big company.

Chairman Keiser: A point of clarification, there are 2 levels of Class B misdemeanors. There is one at the individual & the other at the corporate level. We have to understand what we have here. As I understand it, the PBM or third party payer can be held to this section guilty of Class B misdemeanor which takes it to the corporate level. The corporate level I believe is $20,000 per occurrence.

Jack McDonald ~ Represent Prime Care Therapeutic: The only person that can bring a criminal action is a state's attorney. You are going to have to convince the state's attorney that a crime was committed. I don't think a state's attorney would like all the vague definitions you have put in. I don't think it's workable.

Chairman Keiser: Obviously the courts will decide on these things. Do the corporations get paid the penalty?

McDonald: Yes.

Chairman Keiser: Can you charge the members of the board? In talking with a lawyer, if you make a stupid mistake, you're not liable but if you make an informed mistake, then you have to be careful. We can't take away the authority of the court.

John Olson: I'll answer this way; you can't put a corporation in jail. That's why the organizational fine is the way it is. If there are personal crimes against PBMs who are guilty of intentionally violating these provisions. They are out of state & you are not going to fine anyone who will extradite them for a misdemeanor. As a practical manner, you are dealing with organizational charge. I assume the state's attorney, if they agree to bring a charge, they would bring it against the corporation. If would be handled like civil court.

Chairman Keiser: We have a motion by Rep Becker.

Roll call was taken on the motion to remove subsection 6 on SB 2301 with 6 yes, 8 no, 0 absent, motion failed.

Chairman Keiser: The motion failed. Is there further motion on the bill?

Rep Kasper: Moves a Do Pass as Amended.

Rep Dobervich: Second.

Chairman Keiser: Further discussion?

Roll call was taken for a Do Pass as Amended on SB 2301 with 13 yes, 1 no, 0 absent & Chairman Keiser is the carrier.

3/22/17 DP

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Title.04000

Adopted by the Industry, Business and Labor Committee
March 22, 2017

PROPOSED AMENDMENTS TO ENGROSSED SENATE BILL NO. 2301

Page 1, line 19, replace "A" with "If requested by a plan sponsor contracted payer, a"

Page 1, line 20, replace the second "a" with "the"

Page 2, line 2, remove "fair competition, no self-dealing, and no interference"

Page 2, remove line 3

Page 2, line 4, replace "administrative functions and the mail order pharmacy" with "not participate in a transaction that benefits the pharmacy benefits manager, affiliate, or subsidiary instead of another person owed a fiduciary duty"

Renumber accordingly

Date: Mar 22, 2017

Roll Call Vote #: 1

2017 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2301

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 Becker **Seconded By** Rep Beadle

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser		X	Rep Laning		X
Vice Chairman Sukut		X	Rep Lefor		X
Rep Beadle	X		Rep Louser		X
Rep R Becker	X		Rep O'Brien	Ab	
Rep Bosch	X		Rep Ruby	Ab	
Rep C Johnson	X		Rep Boschee		X
Rep Kasper		X	Rep Dobervich		X

Total (Yes) 4 No 8

Absent 2

Floor Assignment

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

Remove subsection 3, lines 23 & 24 & lines 1-4 page 2

motion failed

11 AM

Date: Mar 22, 2017

Roll Call Vote #: 1

2017 HOUSE STANDING COMMITTEE
ROLL CALL VOTES

BILL/RESOLUTION NO. 2301

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 Beadle **Seconded By** Rep Ruby

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser			Rep Laning		
Vice Chairman Sukut			Rep Lefor		
Rep Beadle			Rep Louser		
Rep R Becker			Rep O'Brien		
Rep Bosch			Rep Ruby		
Rep C Johnson			Rep Boschee		
Rep Kasper			Rep Dobervich		

Total (Yes) ______ No ______

Absent ______

Floor Assignment ______

Voice vote ~ Motion carried

Add on p1, subsection 2 "If requested by a plan sponsor contracted payer"

11 Am

Date: Mar 22, 2017

Roll Call Vote #: 2

2017 HOUSE STANDING COMMITTEE
ROLL CALL VOTES

BILL/RESOLUTION NO. 2301

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 Louser **Seconded By** Rep Bosch

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser			Rep Laning		
Vice Chairman Sukut			Rep Lefor		
Rep Beadle			Rep Louser		
Rep R Becker			Rep O'Brien		
Rep Bosch			Rep Ruby		
Rep C Johnson			Rep Boschee		
Rep Kasper			Rep Dobervich		

Total (Yes) ______ No ______

Absent ______

Floor Assignment **Voice vote ~ Motion carried**

on starting on subsection 3, page 2, line 2, is to remove "agreed to fair competition, no self-dealing, & no interference with prospective economic advantages & establishes a firewall between", we could simply insert, the definition found to self-dealing. We can reference the Black's or put in the whole definition.

11 AM

Date: Mar 22, 2017

Roll Call Vote #: 3

2017 HOUSE STANDING COMMITTEE
ROLL CALL VOTES

BILL/RESOLUTION NO. 2301

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 Becker **Seconded By** Rep Beadle

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser		X	Rep Laning		X
Vice Chairman Sukut		X	Rep Lefor		X
Rep Beadle	X		Rep Louser	X	
Rep R Becker	X		Rep O'Brien		X
Rep Bosch	X		Rep Ruby	X	
Rep C Johnson	X		Rep Boschee		X
Rep Kasper		X	Rep Dobervich		X

Total (Yes) 6 No 8

Absent 0

Floor Assignment **Voice vote ~ Motion** failed

strike on page 2, lines 11 & 12

11 AM

Date: Mar 22, 2017

Roll Call Vote #: 4

2017 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. HB 2301

House Industry, Business and Labor **Committee**

☐ **Subcommittee**

Amendment LC# or Description: 17.0928.03001

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 Dobervich

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser	X		Rep Laning	X	
Vice Chairman Sukut	X		Rep Lefor	X	
Rep Beadle		x	Rep Louser	X	
Rep R Becker	X		Rep O'Brien	X	
Rep Bosch	X		Rep Ruby	X	
Rep C Johnson	X		Rep Boschee	X	
Rep Kasper	X		Rep Dobervich	X	

Total (Yes) 13 No 1

Absent 0

Floor Assignment Rep Keiser

REPORT OF STANDING COMMITTEE

SB 2301, as engrossed: Industry, Business and Labor Committee (Rep. Keiser, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (13 YEAS, 1 NAYS, 0 ABSENT AND NOT VOTING). Engrossed SB 2301 was placed on the Sixth order on the calendar.

Page 1, line 19, replace "A" with "If requested by a plan sponsor contracted payer, a"

Page 1, line 20, replace the second "a" with "the"

Page 2, line 2, remove "fair competition, no self-dealing, and no interference"

Page 2, remove line 3

Page 2, line 4, replace "administrative functions and the mail order pharmacy" with "not participate in a transaction that benefits the pharmacy benefits manager, affiliate, or subsidiary instead of another person owed a fiduciary duty"

Renumber accordingly

2017 TESTIMONY

SB 2301

Testimony of Howard C. Anderson Jr. on Senate Bill No. 2301

January 31, 2017 before the Senate Industry Business and Labor (IBL) Committee. Roosevelt Park Room at 9:30 AM. Senator Jerry Klein Chair.

Chairman Klein and members of the Senate IBL Committee.

The North Dakota Pharmacists Association asked me to introduce this bill to help address some problems they see occurring in their industry. I am a pharmacist myself with a long history in community and hospital pharmacy in North Dakota.

"Specialty drug" is a term being used in the pharmacy industry to identify drugs purportedly needing special handling, strict requirements before prescribing, or filling and refilling prescriptions.

There has been a fairly recent tendency for the Insurance and Pharmacy Benefit Manager industry to attempt to add drugs to the Specialty drug list, which appears to make them eligible to be dispensed only by a specialty pharmacy, often owned by that same insurance company or pharmacy benefits manager.

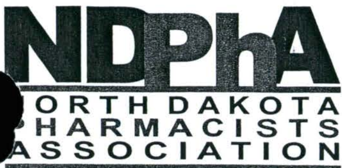
This bill attempts to keep that practice to a minimum and make sure that our community pharmacies can continue to serve their patients as their needs change and their therapy becomes more complex.

Mike Schwab and the pharmacists are here and they will give you information on specific instances and more information on how this bill will help them serve their patients.

Thank you,

Howard

SB2301 1/31/17 #2



SB 2301
Senate Industry, Business and Labor Committee
January 31, 2017 – 9:30 am
Senator Jerry Klein – Chairman

Chairman Klein and members of the committee, for the record, my name is Mike Schwab, the Executive Vice President of the North Dakota Pharmacists Association (NDPhA). We are here today in support of SB 2301.

I will do my best to go through the bill in detail section by section. First, I would like to start off by turning your attention to Page 1 – Line 11 – Letter C. Here you will see a definition of "specialty drug". Some of you might ask, what is a specialty drug? I wish I had an easy answer for all of you. The reality, there is no standard definition of what constitutes a specialty drug. However, the "specialty drug market" is the fastest growing area of the pharmaceutical market. Pharmacy Benefit Managers (PBMs) and insurers have created and maintain specialty drug lists. The problem is that PBMs and insurers all have different lists and in recent years these lists have grown at an extremely fast past. All the of large PBMs here today (Express Scripts, Prime Therapeutics and CVS/Caremark) now all own and control their own Specialty Mail Order Pharmacies. The specialty lists are growing at a rapid pace like never seen before in pharmacy and along with the expansion of so-called "specialty" drug lists prices have followed suit.

Right now, PBMs define and decide which drugs they want to include on these specialty list, when they want to add drugs and how long they will stay on the list. Don't get me wrong, some drugs that are typically administered in a hospital or clinic setting should be considered a specialty drug. However, an ever-growing number of drugs (hundreds of drugs) are being included on these lists that have absolutely nothing "special" about them except their price and local pharmacies cannot dispense them. Retail community pharmacies, hospital community pharmacies and long-term care pharmacies have been dispensing a lot of these drugs for many years and in some cases literally decades. For example, "vancomycin capsules" have recently been added to some of the PBMs specialty pharmacy lists. This drug has been around since 1954 - over 60 years! Pharmacists have been dispensing this drug and providing patient care

long before PBMs even existed in the marketplace. Multiple times, the local pharmacy is prohibited from dispensing specialty medications now. The patient needs to get the medication from one of the PBM owned mail order pharmacies.

The PBMs will lead employers and others to believe that only they can provide specialty drugs. They will lead you to believe that they provide "unique" specialty pharmacy protocols to maximize safety and adherence. I would like to talk to you about those "unique clinical protocols". If you look at their websites or review some of the materials they present to employer groups you will see the following "unique clinical protocols": (1) counsel the patient, (2) provide refill reminders, (3) communicate with your physician, (4) address cost barriers, (5) provide pill splitting, (6) provide utilization reports, and (7) provide educational materials. Chairman and members of the committee, pharmacists have been providing these services daily for many years. There is nothing "unique" about those protocols and those are things pharmacists do every day.

The PBMs will lead you to believe that they can maximize safety by providing the specialty medication through their own mail order pharmacy. I am dumbfounded because the PBM wants you to think that a nurse on the phone who doesn't know the patient, has no patient relationship and is calling from who knows where will do a better job of counseling the patient and showing the patient how to self-administer an injectable drug over the phone or by sending them information to read in the mail. I don't know about you but personally, I would rather have the choice of having my trusted pharmacist show me how to provide the self-injection (which pharmacists are trained to provide!) and be available to counsel me with a face-to-face visit. After all, the local pharmacist year after year is one of the most trusted and most accessible healthcare providers in our healthcare system and this bill aims to keep it that way.

In addition, these drugs that are supposedly so "special" they will just show up in your mail box or be sitting on your front steps (must not be too special if the PBM just throws it in the mail) waiting for you to pick up the phone to talk to someone you hopefully can understand and hopefully already knows your medical health history. There is growing evidence regarding

the amount of waste associated with mail order pharmacies. Patients finding their supposedly specialty drug frozen on their door step in the winter or baking in their mail box during the summer only adds to "waste" in the system and higher costs for the employer or patient paying the bill. We have multiple examples of patients calling their local pharmacist to ask them if they should still take the medication because it was frozen. Thankfully they called their local pharmacist!

Another patient frustration which reduces their quality of life and potential impacts their immediate health is that fact that sometimes the specialty medication does not show up in the mail when it is supposed to or never shows up at all. Of course, when this happens, the local pharmacy provider is now good enough to serve the patient and comes to the rescue. The PBM will provide an override code and allow the local pharmacist to provide an emergency fill or short-day supple of the medication for the patient but only this one time.

They may tell you this bill is going to raise costs. To be honest, that might be true in some circumstances. However, if costs go up, overall there is a high probability that it is because of the PBM not the pharmacy. This takes me into the next provision of the bill. Page 1 – Line 18 – Number 2. You will probably hear each PBM oppose this provision. We understand and can respect their position. This still does not change the reason and rationale for our support of this section.

Chairman and members of the Committee, the public, employers, policymakers and providers have been asking for more transparency in the prescription drug market and more specifically the PBM industry for many years. This provision requires the PBM to disclose to a plan sponsor contracted payer (the employer who is ultimately paying the bill), if there is a difference in what the pharmacy was paid for a drug and what the PBM actually charged the employer. This is called "spread pricing" in the PBM industry (pay the pharmacy low and bill the employer high) and this is where PBMs generate a large portion of their revenue. While not illegal but highly suspect and secret, pharmacies are tired of shouldering the "myth" that community pharmacies often cost more than PBM owned pharmacies. A large number of employers have no idea spreading pricing even takes place. The PBM gets to create the invoices sent to the employer. The employer is not directly billed by the pharmacy nor does the

employer have any idea what the pharmacy was actually paid. This provision would show the employer what the PBM charged them as well as what the community pharmacy was paid. We once heard a PBM lobbyist tell us, if you want us to show the "spread" then we want the pharmacies to show their reimbursement as well. Well, that time has come as we have been backed into a corner and we don't have anything to hide. Not only does this provision provide employers with important information and transparency when they are trying to make an informed contracting decision, but it allows the employer to evaluate if they are getting a fair deal for the services they are buying.

The next set of provisions, Page 1 – Line 22 – Number 3. This provision states the PBM would have to adhere to fair competition, no-self dealing with their administrative functions and the pharmacies that they own and cannot engage in wrongful acts such as breach of contract, misrepresentation, making false or misleading statements against a rival company and would require a firewall between the administrative functions and pharmacy operations of the PBM. Due to their administrative functions as a PBM, they receive all the patient drug information directly from all their competing pharmacies in the country and they need to keep that administrative information separate from their pharmacy business operations. This section might be seen as "given" in a contractual relationship, but we support the clarity of this section.

On Page 2 – Line 4 – Number 4, some PBMs have taken it upon themselves to now require pharmacies jump through a bunch of hoops and become "accredited" to be in the PBMs specialty pharmacy network and to be allowed to dispense specialty drugs to patients. The accreditation requirement is only one aspect of some PBMs attempt to carve pharmacies out of the supposed "specialty" market or other pharmacy networks for that matter. On top of accreditation, some PBMs are also requiring pharmacies adhere to a slew of reporting requirements as well as certain assurance measures. Reporting requirement and assurance measures are one thing. However, a number of the reporting and assurance measures have egregious "fines" attached to them. A pharmacy is already regulated by State and Federal laws and rules and authorized to dispense any and all drugs their licenses and certifications allow.

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We would like to add the following amendment to SB 2301. Create a New Section on Page 2. Add Line 12-13.

12 **SECTION 2. APPLICATION.** This Act applies to contracts and agreements in effect
13 on and after the effective date of this Act.

I would like to thank you for your time and attention today. I would be happy to try and answer any questions. I know there are a number of other individuals who would also like to share testimony with all of you today.

Respectfully Submitted,

Mike Schwab

NDPhA - EVP

SB2301 1/31/17 #3

WRITTEN TESTIMONY OF DAVID A. BALTO TO MEMBERS OF THE NORTH DAKOTA INDUSTRY, BUSINESS AND LABOR COMMITTEE CONCERNING S.B. 2258 AND S.B. 2301

January 31, 2017

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Members of the Industry, Business and Labor Committee, thank you for the opportunity to submit testimony on pending legislation S.B. 2258 and S.B. 2301 and the need increase enforcement and regulation with respect to Pharmacy Benefit Managers (PBMs). This testimony documents the compelling need for this legislation to protect consumers and health care providers, and regulate PBMs in North Dakota. As explained in this testimony, the proposed legislation includes policies that are needed to protect consumers and providers from inconsistent and unfair practices by PBMs and provide a more competitive marketplace.

The comments in this testimony are based on 30-plus years of experience as a private sector antitrust attorney and an antitrust enforcer for both the Department of Justice and the Federal Trade Commission ("FTC"). From 1995 to 2001, I served as the Policy Director for the FTC's Bureau of Competition and the attorney advisor to Chairman Robert Pitofsky. At the FTC, I helped direct the first antitrust cases against PBMs. Currently, I work as a public interest antitrust attorney. I have represented consumer groups, health plans, unions, employers, and even PBMs on PBM regulatory and competitive issues. I have testified before Congress, numerous state legislatures and three times before the Department of Labor on PBM regulation, and was an expert witness for the State of Maine on its PBM legislation.[1]

The following testimony explains why the proposed legislation is necessary to protect consumers, health care providers and competition.

I. Background

PBMs increasingly engage in anticompetitive, deceptive or egregious conduct that harms consumers, health plans, and pharmacies alike. In a nutshell, both consumers and pharmacies suffer as consumers are increasingly denied a choice in their level of pharmacy service by PBMs. PBMs exercise their power to restrict consumers to the PBM's own captive mail order and specialty pharmacy operations, reducing choice and quality for many. Consumers and their health plans also suffer when health plans are denied the benefits of the PBMs' services as an honest broker, which drives up drug costs, and ultimately leaves consumers footing the bill for higher premiums.[2]

Why do consumers care about restricted access to pharmacies? Because community pharmacists are the most accessible health care professionals; and in many markets, such as rural markets which are prominent in North Dakota, they may be the only accessible professional. Because community pharmacies provide consumers with valuable clinical services and counseling, often free of charge. Because some pharmacies offer drugs at lower prices than the PBMs. Egregious PBM conduct jeopardizes these types of programs that consumers highly value. As community pharmacies are already economically efficient and operate on very

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[1] The views expressed herein are my own and do not necessarily represent the views of any individual clients.
[2] Often health plans and large employers are silent on complaining about the PBMs out of fear of retaliation since they must do business with PBMs. In response to criticism during the Express Scripts/Medco merger that employers did not publicly express concern over the merger, Senator Herb Kohl stated that "it is notable that no large employer who privately expressed concerns to us wished to testify at today's hearing, often telling us that they feared retaliation from the large PBMs with whom they must do business." Statement of U.S. Senator Herb Kohl on the Express Scripts/Medco merger (12.6.2011).

minimal margins, reduced consumer access to these pharmacies would, in the end, likely result in harm to other consumers who rely on these community pharmacies.

Similarly, consumers also care about rising health care costs, including out-of-pocket costs for prescription drugs. PBMs have a profound impact upon drug costs. If PBMs are unregulated they can continue to engage in conduct that is deceptive, anticompetitive, and egregious. For this system to work effectively, PBMs must be free of conflicts of interest that arise from owning their own pharmacies. What health plans and employers are fundamentally purchasing is the services of an "honest broker" to secure the lowest prices and best services from both pharmaceutical manufacturers and from pharmacies. When the PBM is owned by the entity it is supposed to bargain with or has its own mail order operations there is an inherent conflict of interest, which can lead to fraud, deception, anticompetitive conduct, and higher prices. The three major PBMs – Express Scripts, CVS/caremark and Optum Rx -- clearly face that conflict since they own mail order operations, specialty pharmacies, and in the case of CVS Caremark – the second largest retail pharmacy chain and the dominant long-term care pharmacy in the U.S.

In recent years, the major PBMs—including those with a clear conflict of interest in their cross-ownership with pharmacies—have engaged in a variety of anticompetitive and anti-consumer practices.

II. Chronic Anticompetitive and Consumer Protection Problems in the PBM Market

PBMs are like other healthcare intermediaries that manage transactions by forming networks and transferring information and money. As a former antitrust enforcer, I can tell you that there are three essential elements for a functioning competitive market: (1) transparency, (2) choice and (3) a lack of conflicts of interest. This is especially true when dealing with health care intermediaries such as PBMs and health insurers where information may be difficult to access, arrangements are complex and clouded in obscurity, and there may be principal-agency problems. On all three of these elements the PBM market receives a failing grade.

Why are choice, transparency, and a lack of conflicts of interest important? It should be obvious. Consumers need meaningful alternatives to force competitors to vie for their loyalty by offering fair prices and better services. Transparency is necessary for consumers to evaluate products carefully, to make informed choices, and to secure the full range of services they desire. In both of these respects the PBM market is fragile at best. There is certainly a lack of choice especially for those plans that are dependent on the top tier big three PBMs (Express Scripts, CVS Caremark and Optum) which have an approximate 80% share of the market. And PBM operations are very obscure and a lack of transparency makes it difficult for plans, including government buyers, to make sure they are getting the benefits they deserve.

When dealing with intermediaries, it is particularly critical that there are no conflicts of interest. A PBM is fundamentally acting as a fiduciary to the plan it serves. The service a PBM provides is that of being an "honest broker" bargaining to secure the lowest price for drugs and

drug dispensing services. When a PBM has an ownership interest in a drug company or has its own mail order or specialty pharmacy dispensing operations, it is effectively serving two masters and may no longer be an "honest broker."

Moreover, when a PBM has its own pharmacy operations there are a myriad of competitive problems. Who will effectively monitor and audit the company-owned pharmacies? A pharmacy chain can use its PBM affiliate to disadvantage rival pharmacies, reducing reimbursement, and excluding pharmacies from networks. What about competitively sensitive information such as prices and costs? Where a pharmacy knows its rivals costs and pricing, it does not have to compete as hard. Ultimately consumers lose through less choice and higher prices.

The rapidly increasing drug costs which effectively lead to higher drug rebates for the PBMs leads one to question which master the PBM is serving. It increasingly appears that PBMs profit from higher drug prices, because they lead to higher rebates.

Competition and choice are crucial for a market to work effectively. North Dakotans should have the choice in how they value pharmacy services. Some choose community pharmacies, others who value one-stop shopping choose their local supermarkets, and others choose chains. This choice is important because competitors have to respond to this choice by improving services and lowering prices.

The legislation presented to this Committee is vital to provide needed protections to consumers, community pharmacies and payors.

Who Speaks for the Consumer – The Community Pharmacist

One important aspect of pharmacy services is the service pharmacists provide in assisting consumers in dealing with insurance companies and PBMs. Too often consumers are lost in a system where the PBM says "we don't have any choice, it's the employer who refuses coverage" and the employer says "we just do what the PBM tells us to do." No one takes responsibility or provides an answer. Who is there to protect the consumer?

The pharmacist is the advocate for the consumer. When PBMs create barriers patients typically seek help from their pharmacist to navigate their pharmacy benefit. Consumers can not battle with the PBM or insurance company. For these consumers, pharmacists act as an advocate, guiding consumers to use the lowest price drugs, explaining co-pays, and determining access. When a particular policy is problematic, the pharmacist will often work through it with the patient, providing explanation and even advocating on behalf of the patient with the PBM—going far beyond the tasks for which the pharmacist is paid.

Moreover, not only are pharmacies not paid for such services, but pharmacies are assessed ancillary fees by the PBMs not provided them at the point-of-sale to consumers. Additionally, in some instances in which the cost of a consumer's co-pay for a drug exceeds the cost of the drug itself, PBMs will claw-back the additional amount from the pharmacy. These practices place pharmacies in a position of not knowing what true reimbursement will be until

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months after they have dispensed the medications.[3] Such practices put pharmacies in peril of being able to continue servicing consumers.

S.B. 2258 provides protection for pharmacies from charges that are not apparent at the point-of-sale or at the time the claim for the dispensed drug is processed by the PBM. It also prevents a PBM from charging a patient a co-pay that exceeds the cost of the medication and prohibits the PBM from automatically clawing-back from the pharmacy the portion of the co-pay that has been patient by the patient. These provisions are necessary to allow pharmacists to continue advocating for patient coverage and protecting patients from egregious PBM practices.

III. A Broken Market Leads to Escalating Drug Costs and Rapidly Increasing PBM Profits

What is the result of this dysfunctional market? PBMs entered the health care market as "honest brokers" or intermediaries between health care entities. However, the role of the PBM has evolved over time and increasingly PBMs are able to — "play the spread" – by not fully sharing the savings they purportedly secure from drug manufacturers. As a result PBM profits have skyrocketed over the past dozen years. Since 2003, the two largest PBMs—Express Scripts/Medco and CVS Caremark— have seen their profits increase by almost 600% from $900 million to almost $6 billion.

If the market was competitive, one would expect profits and margins would be driven down. But as concentration has increased, the exact opposite has occurred.

There is tremendous concern over rapidly increasing drug prices which threaten our nation's ability to control the cost of health care. While PBMs suggest that they are there to control costs, these claims must be carefully scrutinized. The concern of a PBM is to maximize profits and that means maximizing the amount of rebates they receive. Since rebates are not disclosed, this is an incredibly attractive source of revenue. PBMs can actually profit from higher drug prices, since this will lead to higher rebates.

Would PBMs withhold their negotiating punch to secure higher rebates? We do not have to guess that this is occurring. PBMs have used similar strategies in the past. Indeed, as noted below state enforcers have attacked sweetheart deals PBMs arranged with drug manufacturers to force consumers to use higher cost, less efficacious drugs, in order to maximize rebates and secure kickbacks. They held back their negotiating muscle to allow prices to escalate to maximize rebates.

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[3] These practices also increase costs to the federal government. The Centers for Medicare and Medicaid Services (CMS) recently issued a report concerning the ancillary fees known as direct and indirect remuneration. CMS reported that compensation and rebates PBMs receive from transactions beyond the pharmacy point-of-sale is double the rate of gross drug spending by CMS on Medicare Part D prescriptions. Such ancillary charges to pharmacies place more burden on Medicare beneficiary cost-sharing and increasing Medicare's costs for these beneficiaries. CMS, Medicare Part D – Direct and Indirect Remuneration (January 19, 2017), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html.

SB 2301 1/31/17 #3

Facing weak transparency standards, the largest PBMs frequently engage in a wide range of deceptive and anticompetitive conduct that ultimately harms and denies benefits to consumers. Some PBMs secure rebates and kickbacks from drug manufacturers in exchange for exclusivity arrangements that may keep lower-priced drugs off the market. PBMs may switch patients from their prescribed drug to a more expensive drug to take advantage of rebates that the PBM receives from drug manufacturers. PBMs often do not pass through rebates secured from drug manufacturers to payors, and instead are accounted for as a reduction in cost of revenues, allowing the PBMs to hide profits. In fact, Medco was the last PBM to publicly disclose rebates in 2012. In short, PBMs derive enormous profits at the expense of the health care system from the ability to "play the spread" between pharmaceutical manufacturers, pharmacies and health care plans.

No other segment of the health care market has such an egregious record of consumer protection violations as the PBM market. Between 2004 and 2008, Express Scripts and CVS were the subject of six major federal or multidistrict cases over allegations of fraud; misrepresentation to plan sponsors, patients, and providers; unjust enrichment through secret kickback schemes; and failure to meet ethical and safety standards. One of the most common forms of egregious conduct identified was PBMs switching consumers to higher cost drugs, that often were less efficacious, in order to maximize rebates. These cases appended to this testimony, resulted in over $371.9 million in damages to states, plans, and patients so far.

Unfortunately the provisions in the orders in each of these cases have expired, increasing the need for greater regulation and enforcement to ensure that the market functions with transparency, consumer choice, and free of conflicts of interest.[4] These problems are only getting worse. Case in point is the number of recent cases which are either ongoing or have recently settled. In 2014, CVS alone was responsible for over $30 million in penalties concerning violations of the False Claims Act and SEC violations.[5] In 2015, Express Scripts and CVS paid settlement fines to the federal government and to numerous states of over $129 million for illegal prescription dispensing and various violations of the false claims and anti-kickback laws.[6] Currently pending before the Delaware federal district court is a False Claims Act violation brought against Medco (now Express Scripts) on behalf of the U.S., California, Florida and New Jersey over claims the company defrauded state and federal health insurance programs by accepting undisclosed discounts from drug manufacturers and not passing on the savings to its clients, according to a recently amended complaint.[7]

Moreover, substantial private litigation is pending against major PBMs. For example, Optum Rx, has several separate suits filed against it. One by retail chain Kmart which alleged

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[4] For a more detailed analysis of the federal and state cases against the PBMs, *see* David A. Balto, *Federal and State Litigation Regarding Pharmacy Benefit Managers*. http://www.dcantitrustlaw.com/assets/content/documents/PBM/PBM%20Litigation%20Updated%20Outline%20-%201-2011.pdf.

[5] *See* Testimony of David A. Balto, "The State of Comeptition in the Pharmacy Benefits Manager and Pharmacy Marketplaces," before the House Judiciary subcom. On Regulatory Reform, Commercial and Antitrust Law, Appx. A (Nov. 17, 2015), http://dcantitrustlaw.com/assets/content/documents/testimony/PBM%20Testimony. Balto_November%2017%202015.Final.pdf.

[6] Id.

[7] *John Doe v. Medco Health Solutions Inc., et al.*, Case No. 1:11-cv-00684 (D. Del.).

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failure to pay reimbursements for dispensed drugs equating to $38 million in damages;[8] another by 55 independent pharmacies alleging illegal conduct serving to inflate patient costs while simultaneously underpaying pharmacies;[9] and several others filed in 2016 alleging that Optum is overcharging patients for prescription drugs and pocketing the overcharge.[10] Express Scripts is currently facing a $13 billion lawsuit by its largest client Anthem for overcharges for prescription drugs.[11] Additionally, Express Scripts is facing several antitrust conspiracy suits in which plaintiffs have alleged Express Scripts engaged in a conspiracy with other major PBMs to exclude competing compounding pharmacies from their network, effectively forcing the competition to close and routing patients to the PBMs captive pharmacies. These cases have survived Express Scripts' motions to dismiss and one is set for a jury trial beginning in May 2018.[12]

IV. Legislation is Vital to Inform Payors and Protect Consumers

As a general matter it is essential to provide transparency for consumers, which helps them to adequately evaluate products carefully, to make informed choices, and to secure the full range of services they desire. In these respects the PBM market is fragile at best. PBM operations are very obscure and a lack of transparency makes it difficult for plan sponsors to make sure they are getting the benefits they deserve.

Responding to the numerous enforcement actions, both a handful of states and Congress have taken measures to enact transparency provisions by requiring some degree of disclosure of rebates and other revenue. In the multistate enforcement action against CVS Caremark, 30 state attorneys general required rebate disclosure. Additionally, the Department of Labor ERISA Advisory Council recommended PBMs be required to disclose fees and compensation to sponsors of ERISA health plans.[13] Finally, some large sophisticated health plans have negotiated for greater transparency.[14]

Although settlements from litigation and negotiations have helped to address some issues, without legislation, a lack of transparency allows PBMs to "play the spread" – the difference between a PBM's expenditure and the revenue it takes in – leading to higher costs for plan sponsors and patients. PBMs earn enormous profits by negotiating rebates and discounts with drug manufacturers in exchange for promoting certain drugs on their preferred formulary or

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[8] *Kmart Co. v. Catamaran Co.*, Case No. 2015-L-008290 (Ill. Ct. Cl. Aug. 31, 2015).
[9] *Albert's Pharmacy, Inc. et al v. Catamaran Corporation*, Case No. 3:15-cv-00290 (M.D. Pa. Feb. 9, 2015).
[10] *See, e.g, Stevens v. UnitedHealth Group, Inc. et al.*, Case No. 16-cv-03496 (D. Minn.).
[11] *Anthem v. Express Scripts*, Case No. 16-cv-2048 (S.D.N.Y.)
[12] *HM Compounding Services v. Express Scripts*, Case No. 14-cv-01858 (E.D. Mo.); *Precision RX Compounding, LLC et al. v. Express Scripts*, Case No. 16-cv-00069 (E.D. Mo.).
[13] *See* PBM Compensation and Fee Disclosure, Report by the ERISA Advisory Council, Department of Labor (2014), *available at* http://www.dol.gov/ebsa/publications/2014ACreport1.html.
[14] Linette Lopez, The companies you've never heard of are about to incite another massive drug price outrage, Business Insider (Sept. 12, 2016) (reporting that some of America's biggest employers including American Express, Macy's and Coca-Cola have created an organization called the Health Transformation Alliance with the aim of breaking with "existing marketplace practices that are costly, wasteful, and inefficient, all of which have resulted in employees paying higher premiums, copayments, and deductibles every year" including PBMs), http://www.businessinsider.com/scrutiny-express-scripts-pbms-drug-price-fury-2016-9.

engaging in drug substitution programs. PBMs also negotiate contracts with pharmacies to determine how much the pharmacists will be paid for dispensing medication and providing services. By paying a lower reimbursement rate to pharmacies, but failing to adequately disclose reimbursement rates and manufacturer rebates, PBMs can generate more revenue. In both respects, PBMs can "play the spread" by failing to disclose these forms of indirect compensation. The failure to disclose these payments denies purchasers important information that impacts their buying decisions. [15] As a result, this lack of information often results in higher costs for consumers, health plans, employers, and other plan sponsors.

PBMs are free to "play the spread" between manufacturers, pharmacists and plans because of a lack of disclosure. Unclear and inadequate disclosure of rebates and discounts undermine the ability of plan sponsors to compare competing proposals. Because rebates, discounts, and other fee structures remain undisclosed, plan sponsors cannot clearly identify and choose PBMs offering the highest value services. PBMs' promise of controlling pharmaceutical costs has been undercut by a pattern of conflicts of interest, self-dealing, deception, and anticompetitive conduct. The dominant PBMs have been characterized by opaque business practices, limited market competition, and widespread allegations of fraud.

Increased disclosures by PBMs have resulted in price decreases and significant savings for health plans. For example, in the corporate context, a recent report revealed that Meridian Health System discovered that its drug benefit increased by $1.3 million within the first month of contracting with Express Scripts for PBM services.[16] Meridian discovered that they were being billed for generic amoxicillin at $92.53 for every employee prescription; however Express Scripts was paying only $26.91 to the pharmacy to fill these same prescriptions.[17] The result was a spread of $65.62 going back to the PBM. Meridian canceled its contract and switched to a transparent PBM which saved Meridian $2 million in the first year of its contract.

The provision of S.B. 2301 which requires PBMs to provide more transparency for employers and requires the PBM to disclose if the PBM practices spread pricing is vitally important for the employer to make informed contracting decisions to better service its beneficiaries.

V. Protecting Patient Choice and Eliminating Conflicts of Interest

The legislation before this Committee serves to protect patient choice. As consumers and patients we all understand the critical importance of patient choice. Only where consumers have the full range of choices does the competitive market thrive. Unfortunately, because PBMs have their own pharmacy operations – through retail stores, mail order, or specialty pharmacy – they are increasingly engaging in conduct that restricts patient choice and leads to higher costs and worse health care.

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[15] Robert Restivo, Testimony before the Department of Labor ERISA Advisory Council at 15 (August 20, 2014) ("the [PBM] industry is beset with a lack of transparency that is difficult to deal with even for the largest employers."), *available at* http://www.dol.gov/ebsa/pdf/ACrestivo082014.pdf.
[16] Katherine Eban, *Painful Prescription*, Fortune Magazine (Oct. 10, 2013).
[17] Id.

Forcing Consumers to use Mail Order

The major PBMs make a large portion of their profits by forcing consumers to use mail order. The major PBMs often restrict network options to drive consumers to their operations. Mail-order may be more costly, may result in significant waste, and fails to provide the level of convenience and counseling that many consumers require. Consumers may have existing relationships with a community pharmacy and may not wish to leave the pharmacist they know and trust to be served by a mail order robot. Others simply enjoy the ability to one-stop-shop and prefer the convenience of their supermarket pharmacy. The bottom line is that consumers are left worse-off when they are unable to choose the level of pharmacy care they desire.

Preventing Vulnerable Consumers from Using Their Community Specialty Pharmacy

The ownership of specialty pharmacies exacerbates the conflict of interest problem. Restrictive networks raise significant concerns for the over 57 million Americans that rely on specialty drugs.[18] Specialty drugs are typically expensive treatments that require special handling or administration. These drugs provide treatment for our nation's most vulnerable patient populations who suffer from chronic, complex conditions such as hemophilia, Crohn's Disease, Hepatitis C, HIV/AIDS, and many forms of cancer. The leading PBMs – Express Scripts, CVS Caremark and Optum own their own specialty pharmacies and increasingly force consumers to use their specialty pharmacy. Specialty drugs are expected to be the single greatest cost-driver in pharmaceutical spending over the next decade. The cost of specialty drugs is rising rapidly, with a projected increase to $1.7 trillion in 2030.[19]

The dominant PBMs are able to force consumers to use their own specialty pharmacies through restrictive networks. These networks can be higher cost and can also disrupt the continuum of care degrading health outcomes and increasing healthcare costs.[20] Patients on specialty drugs often require regular contact and counseling from their pharmacist. For many disease states, the pharmacist and health care team regularly contact the patient to make sure the drug is properly administered, taken on time, and the drug is working effectively. Disrupting this patient-provider relationship in complex and expensive treatment of very sensitive health conditions imposes significant harm to both the consumer and the health plan. We all know there is a profound difference between the personal treatment of an independent pharmacy and dealing with the automated telephone approach of the large PBMs.

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[18] Laura Hines, *Soaring specialty drug prices leave patients seeking relief*, Houston Chron. (March 15, 2015).
[19] IMS Health, Overview of the Specialty Drug Trend (2014), *available at* https://www.imshealth.com/deployedfiles/imshealth/Global/North%20America/United%20States/Managed%20Markets/5-29-14%20Specialty_Drug_Trend_Whitepaper_Hi-Res.pdf.
[20] The vital service-related role of independent specialty pharmacies was described in my testimony before the United State Senate Judiciary Antitrust subcommittee concerning the Express Scripts-Medco merger. *See* David Balto, Testimony regarding "The Express Scripts/Medco Merger: Cost Savings for Consumers or More Profits for the Middlemen?" before the U.S. Senate Subcommittee for Antitrust, Competition Policy and Consumer Rights, December 6, 2011, *available at* http://dcantitrustlaw.com/assets/content/documents/testimony/SenateJudiciary.ESIMedci.Balto.pdf.

Moreover, restrictive networks and steering practices rob consumers of the choice to use their preferred pharmacy and method of distribution; and—with this important rivalry gone—consumers also miss out on the benefits of vigorous competition, including lower prices and improved service. These restrictive networks deny patients a choice in provider and, given the high-touch nature of services in this area, this choice is highly valued by many consumers. The PBMs' ability to impose restrictive networks harms consumers that depend on the high-cost products and services that are of great, and even life-altering, significance to these vulnerable patients.

Finally, there is the fox guarding the hen house problem. When a PBM has its own specialty pharmacy, it no longer clearly serves the plan – rather, its incentive is to increase profits by forcing consumers into the PBM's specialty pharmacy.[21] The New York Times poses the appropriate question: "pharmacy benefit managers like CVS and Express Scripts…are supposed to help health plans control drug costs. But will they have the zeal to do that if they are making money dispensing these expensive medicines?"[22]

Of critical importance here is the fact that North Dakota community pharmacists are not looking for a "handout" from the PBMs, the state or the federal government; they simply want the ability to compete on a level playing field. This further demonstrates the anticompetitive practices utilized by the PBMs. If a small business community pharmacy is willing to accept the same contract terms as, for example, CVS, but is denied the opportunity to contract, one of two things is happening: either CVS's contract is raising costs for consumers by not offering the lowest price true competition would yield, or consumers are needlessly suffering poorer pharmacy access and choice.

The provisions of S.B. 2258 and S.B. 2301 serve to help eliminate many of the conflicts of interest explained above. The legislation allows a pharmacy to mail or delivery medications as an ancillary service of the pharmacy. This is a practice that North Dakota pharmacists have been providing for over 125 years. Additionally, the legislation provides increase in patient access and choice for patients purchasing specialty medications. By preventing the PBMs to require standards more stringent than federal and state requirement for licensure in the state of North Dakota, and allowing a licensed pharmacy to dispense any and all drugs under that license, the legislation will help ensure adequate pharmacy access and choice for North Dakota consumers.

VI. Conclusion

S.B. 2258 and S.B. 2301 will have a significant, positive impact on North Dakota consumers, providers and employers. PBMs operate with little transparency and inherent conflicts of interest engaging in deceptive practices. Without transparency, PBM profits will

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[21] Katie Thomas, Specialty Pharmacies Say Benefit Managers Are Squeezing Them Out, New York Times (Jan. 9, 2017), *available at* https://www.nytimes.com/2017/01/09/business/specialty-pharmacies-say-benefit-managers-are-squeezing-them-out.html.

[22] Andrew Pollack and Katie Thomas, Specialty Pharmacies Proliferate, Along With Questions, New York Times (July 15, 2015), *available at* http://www.nytimes.com/2015/07/16/business/specialty-pharmacies-proliferate-along-with-questions.html?_r=0.

continue to rise exponentially at the expense of small business pharmacies and patients. Broadening transparency requirements on PBMs will allow pharmacies to better ably serve their patients by being able to receive fair reimbursement, and allow payors and employers to make informed contract decisions before it enters a deal with the PBM. Conflicts of interest in owning mail and specialty pharmacies significantly inhibit patient choice and access to their preferred providers. Allowing increased choice and access to community pharmacy will foster greater competition to the benefit of plans and ultimately to consumers. We urge you to vote to pass both S.B. 2258 and S.B. 2301.

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Appendix A: Cases against Pharmacy Benefit Managers

Appendix A offers a summary of cases against pharmacy benefit managers ("PBMs"). This is not a complete list of all litigation against PBMs. The case summary focuses on cases claiming PBM deception, fraud, or antitrust violations.

Year	Case	Summary
2016	*PRIME AID Pharmacy Corp., v. Express Scripts, Inc. No: 2:16-cv-02182*	PRIME AID Pharmacy files antitrust law suit against Express Scripts for fraudulent scheme and anticompetitive behave between specialty pharmacies and the specialty pharmacies that Express Scripts owns and operates.
2016	*CVS Caremark Corp. v. Prime Therapeutics Inc., No: 0:15-cv-04570-DWF-TNL*	CVS is seeking $19 million from Prime Therapeutics for alleged underpayment for generic drug reimbursements and did not act in good faith.
2016	*Express Scripts receives subpoena from U.S. Attorney's Office for the District of Massachusetts*	U.S. Attorney Office seeking information about Express Scripts relationship with drug makers, charitable foundations they own that and provide assistance to federal health care program beneficiaries and specialty pharmacies.
2016	*Express Scripts receives subpoena from the U.S. Attorney of New York*	U.S. Attorney's office seeking information about the firm's relationship with drug makers and prescription drug plan clients and payments schemes to and from both.
2016	*Richard Medoff v. CVS Caremark Corporation, et al., No: 1:09-cv-00554-JNL-PAS*	Medoff and class action suit against CVS Caremark for False and Misleading Statements related to its merger and profitability. Settlement issues in the sum of **$48,000,000 Million in damages.**
2016	*Anthem v. Express Script, Inc.*	Anthem has accused Express Scripts of breaching their management services agreement by charging inflated prices and refusing to renegotiate in good faith. Among the several additional claims, Anthem said Express Scripts didn't properly comply with regulations set out by the Centers for Medicare & Medicaid Services regarding Medicare Part D claims. Anthem is seeking **$15 Billion in damages.**
2016	*Burnett v Express Scripts, Inc. S.D.N.Y., No. 1:16-cv-04948*	Express Scripts Inc. and Anthem are accused in a proposed class action of breaching their ERISA fiduciary duties that caused the plan participants to overpay for benefits. Brought by plans sponsored by Verizon Communications Inc., AmTrust Financial Services and LG&E and KU Energy LLC and their 26,000 combined participants.

2016	*Trone Health Services Inc et al. v. Express Scripts No.4:16-cv-01250-RLW*	Trone Health Services Inc on behalf of all similarly situated pharmacies in the United State alleging Unfair Competition. Breach of Contract, Breach of Implied Covenant of Good Faith and Fair Dealing, Interference with Economic Advantage, Violation of Uniform Trade Secrets Act and Fraud for the practice of "slamming" to personally enrich Express Scripts. Trial by jury date not set yet.
2015	*United States ex rel. DiMattia et al. v. Medco Health Solutions, Inc.*, No. 13-1285 (D. Del.).	The United States alleged that Medco (now part of Express Scripts) violated the False Claims Act. In particular, it was alleged that Medco solicited remuneration from AstraZeneca in exchange for identifying Nexium as the "sole and exclusive" proton pump inhibitor on certain of Medco's prescription drug lists. As a result of this deal, Medco received reduced prices on AstraZeneca drugs: Prilosec, Toprol XL and Plendil. Medco settled the case and **agreed to pay $7.9 million** to resolve the kickback allegations.
2015	*Kmart Co. v. Catamaran Co.*, No. 2015-L-008290 (Ill. Ct. Cl.)	Kmart alleges that Catamaran "improperly manipulated prescription reimbursements." In particular, Kmart alleges that Catamaran cut payments to Kmart pharmacies and failed to reimburse Kmart for almost 28,000 pricing appeals. As a result of these pricing appeals, Kmart has **suffered $38 million in damages**. This case is ongoing.
2015	*Albert's Pharmacy, Inc. et al v. Catamaran Corporation*, Civ. No. 3:15-cv-00290-UN2 (M.D. Pa.)	Fifty-five independent pharmacies sued Catamaran for illegal conduct. The parties allege that Catamaran inflated patient costs while simultaneously underpaying pharmacies. Specifically, the pharmacies argue that Catamaran set rates below cost, made pricing data inaccessible, did not update data, and provided no transparency on how drugs rebates are applied. As a result of Catamaran's practices, the pharmacies' business and continued delivery of patient care are at risk. This case is ongoing.
2015	*U.S. ex rel., et al. v. Novartis Pharmaceuticals Corp.*, No. 1:11-cv-08196 (S.D. N.Y.)	The United States sued Accredo (owned by Express Scripts) claiming that Accredo recommended the drug Exjade to Medicaid patients in exchange for kickbacks from Novartis Pharmaceuticals Corp., which markets the drug. **Accredo settled the matter paying $60 million to the federal government and various states.**
2015	*John Doe v. Medco*	A relator on behalf of the United States, California,

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	Health Solutions Inc., et al., Case No. 1:11-cv-00684 (D. Del.)	Florida and New Jersey brought a False Claims Act case against Medco. The case claims Medco (now a part of Express Scripts) defrauded state and federal health insurance programs by accepting undisclosed discounts from drug manufacturers and not passing on the savings on to its clients. This case is ongoing.
2015	*HM Compounding Services v. Express Scripts*, Case No. 14-cv-01858 (E.D. Mo.)	Express Scripts is facing an antitrust conspiracy suit in which the plaintiff a compounding pharmacy, has alleged Express Scripts engaged in a conspiracy with other major PBMs to exclude competing compounding pharmacies from their network. As a result, competition within the compounding industry has been foreclosed and consumers have been routed to the PBMs captive pharmacies. The case is ongoing, and the plaintiffs have survived a motion to dismiss.
2015	*United States v. CVS* See: http://goo.gl/Ks3FqR	CVS was forced to **pay $22 million** to resolve federal allegations that its pharmacies sold narcotic painkillers not prescribed for legitimate medical purposes.
2014	*Grasso Enterprises, LLC, et.al., v. Express Scripts, Inc.*, Case No: 4:14-cv-01932 (E.D. Mo.)	Numerous compounding pharmacies sued Express Scripts alleging that the company intentionally cut compounding spending and illegally terminated compounding pharmacies from the Express Scripts' network. This case is ongoing.
2014	*United States ex rel. Well v. CVS Caremark, Inc.*, Civil Action No. SA:11-CV-00747 (W.D. Tex.).	The United States filed a False Claims Act suit against Caremark for knowingly failing to reimburse Medicaid for prescription drug costs paid on behalf of Medicaid beneficiaries who also were eligible for drug benefits under Caremark-administered private health plans. Caremark settled the case, **paying the federal government $6 million.**
2014	*Securities and Exchange Commission v. CVS Caremark Corp.*, Civil Action No. 14-177-ML (D.R.I.)	Stemming from 2009, CVS Caremark agreed to **pay $20 million** to settle charges brought by federal securities regulators that it misled investors and committed accounting violations.
2012	*Uptown Drug v. CVS Caremark*, Case No. 12-cv-6559 (N.D. Cal.)	Class of independent pharmacies filed suit against CVS Caremark alleging violations of California's unfair trade practice law by forcing maintenance prescriptions adjudicated by CVS Caremark's PBM business into CVS retail pharmacies, to the detriment of California pharmacies. The case is pending before the Ninth Circuit Court of Appeals.
2012	*In the Matter of CVS*	The Federal Trade Commission filed a complaint

	Caremark Co., FTC No. 112 31210	against CVS Caremark for misrepresenting the prices of certain Medicare Part D prescription drugs at CVS and Walgreens pharmacies. The misrepresentation caused seniors and disabled consumers to pay significantly more for critical medications. CVS Caremark settled, **paying refunds to 13,000 consumers for a total of $5 million.**
2009	*HHS v. CVS* See: https://goo.gl/tHlXcM	CVS agreed to **pay $2.25 million** to resolve allegations by both the Department of Health and Human Services and Federal Trade Commission that it violated the Health Insurance Portability and Accountability Act (HIPAA).
2008	*Washington v. Caremark Rx.*, No. 08-2-06098-5-SEA (Wash. Sup. Ct.)	29 attorney generals, including the Washington Attorney General, alleged that Caremark engaged in deceptive trade practices, did not inform clients of retained profits from drug switches, and improperly restocked and reshipped previously dispensed drugs. Caremark settled the matter **paying $41 million** to the states and agreed to a change in business practices.
2008	*In re Express Scripts, Inc. PBM Litigation*, No. 4:05-md-1672-HEA (E.D. Mo.)	Numerous states sued Express Scripts alleging numerous violations of consumer protections. The violations included deceptive business practices by illegally encouraging doctors to switch patients to different brand name medications and increased spreads and rebates from manufactures without passing the savings onto the plans. Express Scripts **paid $9.3 million** to settle the case, accepted restrictions on its drug switching practices, and adopted a code of professional standards.
2006	*United States of America v. Merck-Medco Managed Care L.L.C., et al.*, No.: 00-cv-737 (E.D. Pa.)	A multistate whistle blower lawsuit filed against Medco for violations of both federal and state False Claims Acts alleging defrauding the government, increasing drug prices, and failing to comply with state-mandated quality of care standards. Medco settled and **paid a total of $184.1 million**.
2005	*United States of America, et al. v. AdvancePCS, Inc.*, No. 02-cv-09236 (E.D. Pa.)	A whistleblower suit against Advanced PCS (now a part of CVS Caremark) alleged that Advanced received kickbacks from drug manufacturers, induced customers to sign contracts with the PBM, and submitted false claims. Along with a **$137.5 million in settlement**, Advanced received a five-year injunction and was forced to enter into a Corporate Integrity Agreement.

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Senate Industry, Business and Labor Committee
Senator Jerry Klein, Chairman
600 E. Boulevard Ave.
Bismarck, North Dakota 58505

Dear Committee Members,

My name is Dr. Erik Christenson, PharmD and Chief Professional Officer at Heart of America Medical Center. I oversee the Pharmacy, Physical Therapy, Occupational Therapy, Laboratory, Radiology, Respiratory Therapy and Clinical Dietary Departments at our hospital. I am writing this letter in support of SB 2301.

After completing my residency in General Hospital Pharmacy I moved to the community of Rugby, North Dakota. I have lived in this community for close to 17 years. My wife and I have raised our family in this community. My wife works at the Heart of America Medical Center. I have three children, two of which have graduated from Rugby High School and are now attending in-state universities and the third is just finishing up 6th grade. I have grow to cherish and love my community and our local healthcare system. I became the Director of the Pharmacy Department at HAMC about nine years ago and I was recently promoted to an administrative position as the Chief Professional Officer; this is in addition to my Director of Pharmacy duties. Over my tenure of Pharmacy Director, we have grown the department from a team of two employees to a pharmacy care team of 11! We provide a wide range of care to our local community including: Outpatient infusions, outpatient retail pharmacy services, long term care pharmacy, diabetic shoes, specialized compliance packaging, medication reconciliation and medication therapy management as well as many other needed services in our community.

However, we are seeing a disturbing trend in the insurance industry and it is a trend that threatens the very existence of our local healthcare systems. Many insurance companies now own or have established relationships with for-profit mail order pharmacies. These pharmacies are using a variety of tactics to take all reimbursable pharmacy care away from our local communities. The insurance companies are forcing our patients to get their medications from these out of state mail order pharmacies. In our local, small hospitals we basically have four main sources of revenue. These help cover the costs of several areas of care that do not generate enough revenue to contribute to supporting the hospital system. These four areas are normally Surgery, Physical/Occupational Therapy, Radiology and Outpatient Pharmacy. Now, the insurance companies are taking away one of the revenue sources from our healthcare systems. This could irreparably harm our local, community-based healthcare systems and prevent us from having the resources needed to provide quality care to our patients and communities.

In a community such as Rugby with a population of about 3,000 our healthcare system is the major employer in town with approximately 389 employees. So, not only do these practices by out of state for-profit companies hurt our patients by decreasing our resources, these practices also threaten the very existence of our communities as we know them.

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I do not want to take up too much of your time so I will provide a summary of the issues at hand and then close with why this Bill is beneficial to North Dakota and its communities.

Issues at hand:

1. **These companies are harming our patients.** By not allowing our patients to utilize their local healthcare providers and pharmacies, the Pharmacy Benefit Managers (PBMs) and the pharmacies they own or have relationships with are creating situations that could lead to potential patient harm. I have dealt with multiple situations of potential or actual harm to patients because of noncompliance with medications, improper storage of medications or lack of professional guidance on the use of medications. These situations can be directly linked to the mail order practices of out of state pharmacies. Mail order is not a good model for patient care and safety. I am constantly working with patients that have problems with their mail order medications. Patients have trouble reaching anyone at the mail order pharmacy that can help them when they have questions, they do not receive their mediations on time and at times they don't know why they were sent a certain medication. Patients do not have anyone conveniently available in the pharmacy to discussion their questions or concerns regarding their medications.
2. **These companies are not driven by healthcare professionals, but by for-profit motives.** Do not allow these for-profit companies to remove healthcare access from our rural communities. We need to empower our local health professionals to provide care. Our health professionals have taken an oath to care for our patients according to the best care standards available. We have too many examples of large, for-profit corporations putting aside the health and well being of our citizens for the almighty dollar.
3. **These companies say they will save our businesses money. However, our healthcare system utilized one of these large PBMs and we were never shown the savings given to our hospital or our employees.** Our premiums have continued to go up and our deductibles have continued to increase. The PBM will not show us how much they are actually paying the mail order pharmacies and how much they are charging us to manage our pharmacy benefit. This practice of "spread pricing" is one way many of these PBMs are making huge profits at the expense of our patients. Our facility has also seen firsthand that the hospital's prescription benefit plan is charged essentially the same amount for the prescription whether it is filled locally or at the out of state mail order pharmacy. So I ask you, where are the savings? If the PBMs are supposed to be saving the consumer money as well as cutting costs, how are they making record profits? Express Scripts alone made over $100 billion last year! How do they afford all of the lobbyist that fly into our state to take away our healthcare? The cost of prescription drugs continues to sky rocket and yet our local pharmacies are making less and less every year. The money is obviously going somewhere other than to our local pharmacies. There is mounting evidence that these drug "middle men" or the PBMs are taking a large amount of the profits. Not only do they take our resources, they also increase the costs of providing care because of all the mediation misadventure caused by the mail order system.

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4. **These practices are costing our local healthcare systems hundreds of thousands of dollars.** Our 340B drug pricing program provides Heart of America Medical Center with about $700,000 annually. We use this revenue to keep our ER open and operational, provide diabetic education specialist services and operate a local paramedic/ambulance service; all of which would not be possible without these types of funds. However, these funds only come from prescription utilization at a local outpatient pharmacy, whether hospital or retail based. We do not receive these funds if an out of state mail order pharmacy fills our patient's prescriptions. It is also noteworthy that 340B funding is best for "specialty" medications. However, the push by PBMs to use out of state for-profit pharmacies is taking away those much needed funds/ revenue from our local communities.
5. **If we allow the out of state pharmacies to take all of the resources out of our communities, not only will we not have access to local quality healthcare services as we do now, we will also not be able to employ many of the professionals we need.** What does it matter to our employees and community if the PBMs save us a few dollars here and there if in the end we lose hundreds of thousands of dollars every year in revenue to our local community and our jobs? If we lose our local healthcare services and facilities along with our healthcare professionals, we will also eventually lose our communities.

Again, this is just a sampling of the issues PBMs are causing for healthcare delivery in our small rural communities. SB 2301 will go a long way to help stop these abuses and diversion of resource from our communities. I urge you to pass SB 2301 and help save our rural communities in North Dakota.

Erik Christenson, PharmD
Chief Professional Officer
Heart of America Medical Center
800 S. Main Ave
Rugby, ND 58368

Senate Industry, Business, and Labor Committee

Chairman – Sen. Jerry Klein

SB 2301 Hearing (Specialty Pharmacy)

01/31/2017

Chairman Klein and members of the Committee. I am Dan Churchill, a pharmacist from Bismarck. I am here today to urge you to issue a DO PASS recommendation on SB 2301.

SB 2301 will add some common sense language to the North Dakota century code regarding what medications a licensed Pharmacist may dispense. The State Board of Pharmacy licenses pharmacists to dispense prescription drugs. Unfortunately too many times in today's healthcare marketplace an insurance company or Pharmacy Benefits Manager (PBM) dictates what we as pharmacists are qualified to dispense. Insurance PBMs also decide what they are going to define as a specialty medication. SB 2301 will define what a specialty medication is in the state of North Dakota.

In my practice we have patients that have been getting the same Specialty medication from our pharmacy for over 10 years and now we have to tell them that their PBM no longer considers us qualified to dispense the medication and you will have to get it from the Mail-order pharmacy that the PBM owns. The patient then needs to contact the Mail Order pharmacy and coordinate with the prescriber and then coordinate when and where to get the product shipped too. One patient said he has to have it delivered to his work, because there is no one at home during the day to receive the shipment. And you don't exactly want a $10,000 medication sitting on the front porch in a North Dakota winter when it is 20 below. Or a North Dakota summer for that matter when it is 95 above. So much for patient privacy when you have no choice but to have your prescriptions delivered to your work. One patient asked if the he could have the Mail order pharmacy ship it to our pharmacy so he could pick it up from us. While I agreed with him that it was probably the safest and most effective way to dispense the medication, I told him that the PBM Mail order pharmacy probably would not agree to that.

SB 2301 will return to the State Board of Pharmacy the authority that was given to it by the State: To determine who has the qualifications to dispense medications.

I urge you to issue a DO PASS recommendation on SB 2301 and bring common sense back to the specialty medication marketplace in North Dakota

Thank you,

Daniel M. Churchill, Pharm.D., R.Ph

SB 2301 1/31/17 #7

Senate Industry, Business, and Labor Committee

SB 2301 – 9:30 A.M.

01/31/17

Chairman Senator Jerry Klein

Chairman and members of the committee, for the record, my name is Gary Boehler, a pharmacist consultant employed by Dakota Drug, Inc., a regional drug wholesaler based in North Dakota, and serving many independent pharmacy owners in North Dakota and surrounding states. I am here today to speak in support of SB 2301.

I have been asked to comment on SB 2301 given my knowledge and past experience with PBM practices throughout the industry and to comment on language contained in SB 2301.

Specialty medications are the fastest growing area of the pharmacy market. Many of these drugs are higher cost medications, require more attention to detail by the patient, and thus more direct interaction by a local pharmacist to help ensure patient compliance and therefore, the desired outcomes from these medications. Currently, pharmacy benefit managers (PBMs) own their own specialty pharmacy mail order operations and in many instances prevent a local retail community pharmacy, hospital pharmacy, or local long term care pharmacy from dispensing these "specialty" medications. I have purposely put the word specialty in italics because in many instances, the word is being used loosely by the PBM industry as a

means of preventing a local pharmacy from dispensing these medications. For example, the drug vancomycin, an antibiotic that has been dispensed by pharmacies across the country is suddenly being categorized as a specialty drug and local pharmacies receive a reject notice from the PBM when the claim adjudication process is attempted. Many of these specialty drugs are heat labile or sensitive to freezing. It makes no sense to have these specialty drugs sit in a patient's mailbox when the temperature outside is 95 degrees, and by contrast, 10 degrees below zero! That is precisely what happens with mail order.

SB 2301 will provide a significantly higher level of safety to patients who require expensive and life changing medications. A local pharmacist will provide far more oversight with these patients than some central mail order facility 1,200 miles away, and the patient can feel comfort in knowing his/her medication will be <u>there on time.</u> For that reason I support SB 2301.

SB 2301 prevents PBMs from deeming some generic drugs or other medications that have been routinely dispensed for years by retail pharmacists as specialty medications and preventing a local pharmacy from dispensing these medications. It amounts to nothing more than a restraint of trade. For that reason I support SB 2301.

SB 2301 provides more transparency for employers who are paying these bills and requires all PBMs to disclose to the employer when and if a PBM engages in spread

pricing (i.e., charging the employer more for that same prescription than the PBM pays to the participating pharmacy). Note that this does not make the practice of spread pricing illegal, but allows the plan sponsor to make an informed decision about contracting. For this reason I support SB 2301.

As I stated earlier in the hearing for SB 2258, this SB 2301 also prevents a PBM from implementing credentialing standards that are more stringent or inconsistent with federal and/or state laws that allow licensed pharmacists in good standing to dispense specialty medications in the state of North Dakota. For that reason, I support SB 2301.

There is nothing in the practice of dispensing that can replace the "face-to-face" experience patients have with their local pharmacist, whether or not the medication is routine or a more complex regimen as with some of the drugs now being classified as specialty. PBM mail order facilities resist patient consultation, even by telephone! There is every reason to believe that face-to-face (via video conferencing) is even far less likely with a PBM owned central fill model. Patients deserve far more attention than what is offered by PBM owned mail order and specialty pharmacy settings today. For that reason I support SB 2301.

The high cost of specialty medications is a primary driver for the exclusions of local pharmacies from filling this newer class of medications. The spread pricing that occurs here with a plan sponsor is extremely high and yet another reason for the

unrealistically high costs of PBM driven medications. For that reason I support SB 2301.

Thank you Mr. Chairman and committee members for allowing me to present this testimony on behalf of North Dakota pharmacists and pharmacies.

Gary W. Boehler, R.Ph.

SB2301NDSENATE2017

SB 2301 – SENATE INDUSTRY, BUSINESS & LABOR COMMITTEE – JANUARY 31, 2017

Good morning Mr. Chairman and members of the committee. My name is Abigail Stoddard, I am pharmacist for Prime Therapeutics. I am here this morning to respectfully oppose SB 2301.

First and foremost, SB 2301 would remove our ability to selectively create specialty pharmacy networks. Specialty pharmacy networks keep patients safe, ensure they have reliable access to medications and specially trained pharmacists, and are a key cost control tool to combat the rising costs of life saving drugs.

Specialty drugs require care coordination using personnel specifically trained in the disease states treated by the drugs. These personnel work with the patients and physicians to address side effects, drug interactions, and track the outcomes for specific patients. These standards of care are not accounted for in a typical state pharmacy license and require extra credentialing by independent third parties such as URAC. I'd like to illustrate this with specific example – Remodulin – a drug used to treat pulmonary arterial hypertension. This drug comes in a simple vial.

Each dose of the drug, however, must be given to the patient along with needles, syringes, alcohol swabs, bandages, herparin flushes, sodium chloride flushes, sterile water, and an infusion pump. As you can imagine, this also requires the patient get the correct instructions on how to prepare the drug, use the pump, care for their IV lines and have a provider available 24/7 should they need help. Using a specialty pharmacy ensures our health plans that these patients receive the attention and care coordination needed to use these drugs safely and effectively.

In addition to being a complicated drug to use each vial costs approximately $3,000 and a patient may multiple vials each month. Specialty pharmacies are an important channel that can exact leverage from the drug manufacturers to lower prescription drug costs. In North Dakota Prime's specialty pharmacy network is projected to save our client's approximately half a million dollars in 2017. The $3,000 price tag I just mentioned may sound like a lot, but that is just the beginning.

New specialty drugs enter the market every day, and there is no ceiling on their cost. Take the last 6 drugs approved by the FDA in 2016 – 5 of them were specialty drugs, the last of which made headlines around the country as being the not only first treatment for spinal muscular atrophy but also for its price tag of $750,000 a year. Our clients want to cover block-buster drugs like this for our members, and specialty pharmacy networks are an essential tool to drive discounts and contain costs so they are able to do so.

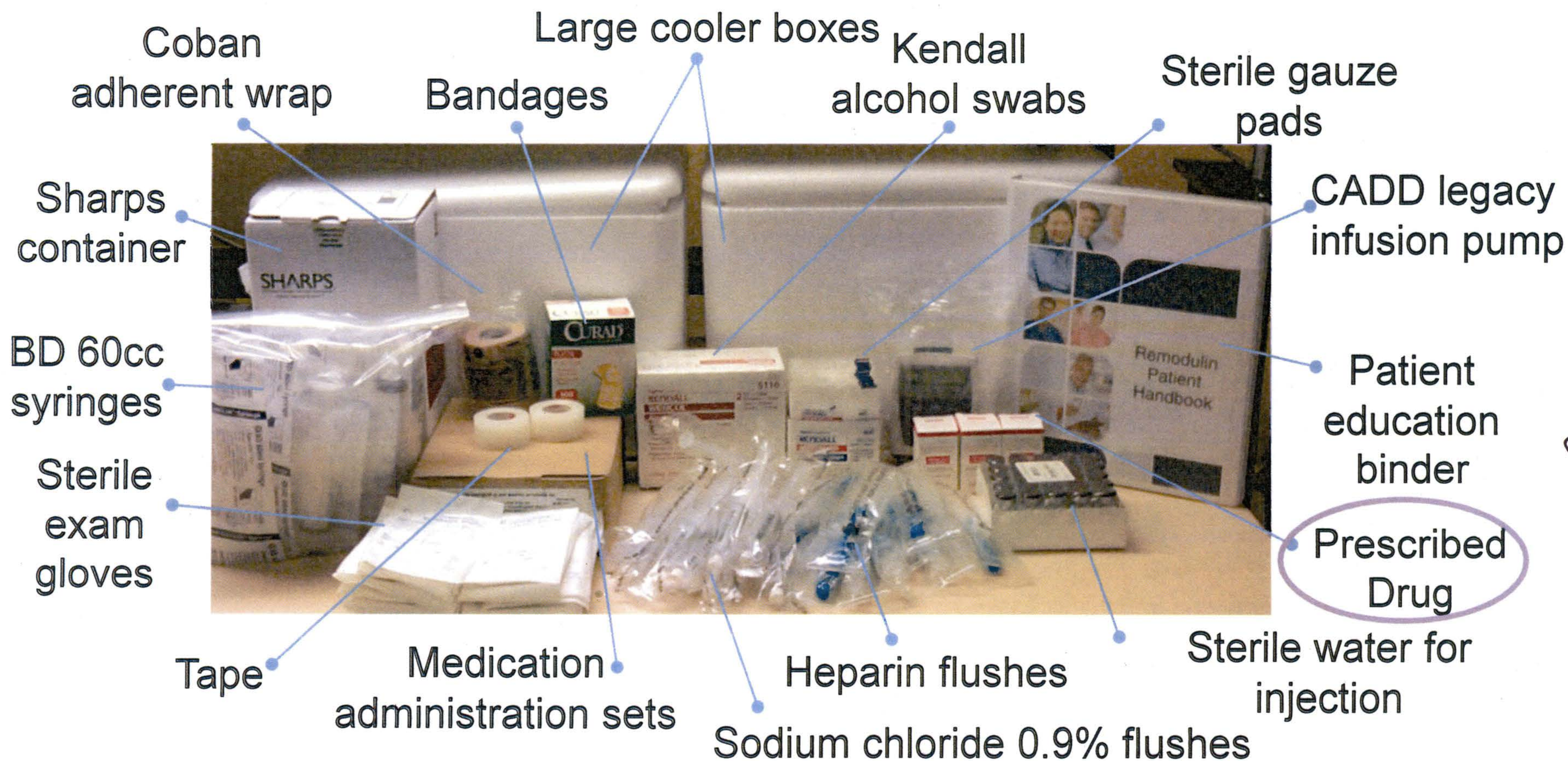
(OVER)

When similar legislation was considered in Minnesota it received a fiscal note estimating the cost to the state at $7.8 million dollars over the next 2 years.

Lastly, sections 2 and 3 of the bill address the contracts PBMs have with their clients. North Dakota code chapter 26.1-27.01 and 26.1-27.1 already specify transparency requirements in PBM-client contracts, including our affiliation with entities providing pharmacy services. Further state interference in these agreements is not necessary.

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

What's so different about specialty drugs?



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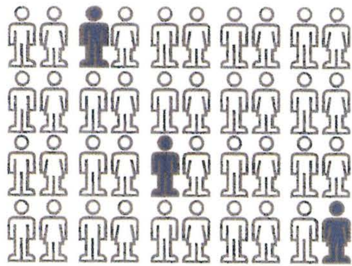
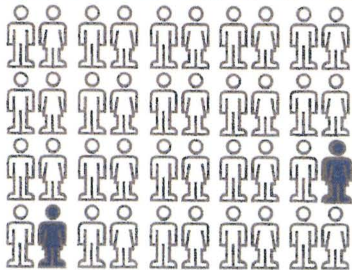
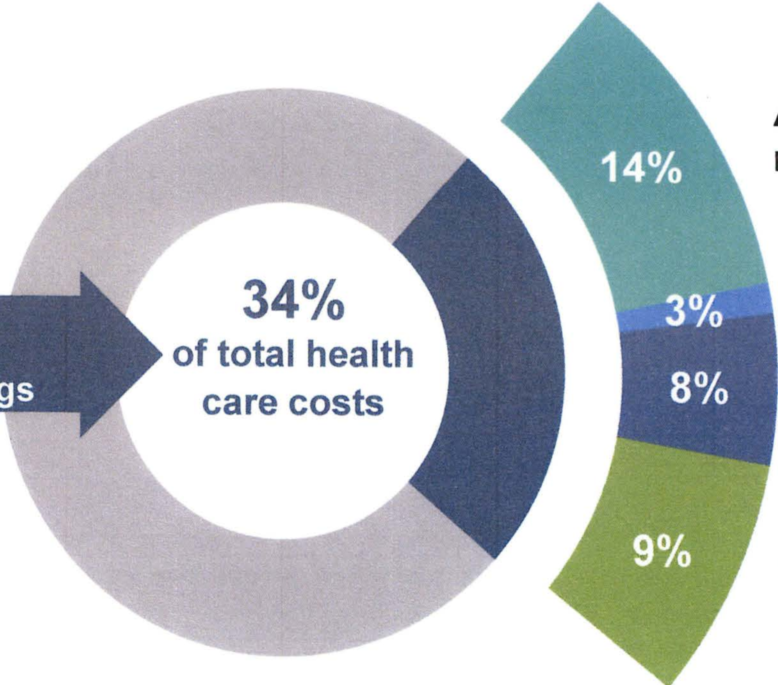
Specialty Patients are Complex and Drive a Large Portion of Health Care Costs



5.1%
of members use specialty drugs





All other medical costs

All other drugs

Specialty condition: other medical costs

Specialty drugs

Source: CVS Specialty Analytics, 2016 analysis of 2015 Blue Health Intelligence Commercial Specialty Drug Database

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SB 2301 1/31/17 #10

Testimony of Pat Ward in Opposition to SB 2301
Senate IBL – Tuesday, January 31, 2017 – 9:30 a.m.

- Good morning, Chairman Klein and members of the Senate IBL Committee. My name is Patrick Ward, and I am here on behalf of Express Scripts – one of the nation's largest pharmacy benefit managers – in opposition to SB 2301.

- As a pharmacy benefit manager, it is our goal to make prescription drugs safer and more affordable for our clients, as well as their beneficiaries. PBMs do this in a variety of ways: by negotiating discounts from brand drug manufacturers, designing retail pharmacy networks, promoting generics, operating specialty pharmacies, providing formulary management, performing drug utilization reviews and so forth.

- ESI performs these services for tens of millions of Americans through our clients -- including Fortune 500 employers, health plans, labor unions and government entities of all sizes.

- Our clients design their pharmacy benefits to meet the unique needs of their respective workforces. We, then, as a PBM, administer that benefit. The details of how that benefit is structured, including the pharmacy network, are determined by the plan sponsor/client. These are sophisticated contracts negotiated by knowledgeable experts with great resources.

- We are here in opposition to SB 2301. Specifically, parts 3, 4, and 5 of section 1, all serve to eliminate specialty pharmacy networks as an option for plan sponsors when designing their benefits. Whether clients want fewer pharmacies in their network, or whether they want a specific network of specialty pharmacies for their beneficiaries, this legislation would prohibit that freedom of contract. Narrow, or even specialty, networks can offer savings opportunities for clients and patients, as well as offer specialized care. Moreover, certain federal REMS (risk evaluation and mitigation strategies) programs and even some drug manufacturer agreements require limited distribution of specialty products – because only a small subset of pharmaices – specialty pharmacies – are equipped to store and dispense these products. This legislation contravenes those principles.

- Specialty drugs are used to treat rare diseases and may not be stocked at typical brick-and-mortar drug stores. Given the sophisticated handling and distribution requirements of specialty drugs, the number of facilities equipped to handle the needs of specialty patients is lower still. Of the 69,000 pharmacies in the United States, relatively few qualify as specialty pharmacies. Since not all pharmacies provide the same level of clinical care and product support to ensure that patients have access to the right medications at the right time, ***payers must differentiate which pharmacies provide***

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comprehensive specialty care versus those unable to achieve similar service levels and outcomes.

- Unlike traditional brick-and-mortar drugstores, specialty pharmacies employ highly trained teams of pharmacists, nurses, and clinicians (with disease state expertise) to work with doctors and patients to ensure those complex medications are administered on time, conveniently, safely and effectively.

- Specialty pharmacies provide a broad range of services that help patients with unique needs, including:
    - Providing around-the-clock access to specially trained clinicians who offer patients guidance and insight on disease states, as well as the use of specialty drugs;
    - Consulting directly with physicians to address patient side effects, adverse drug reactions, non-adherence, and other patient concerns;
    - Performing disease and drug-specific patient care management services;
    - Collecting data and tracking outcomes for specific patients;
    - Managing patient adherence and persistency of drug regimens; and,
    - Managing care for manufacturer REMS program requirements, including reporting, Phase IV trials, the dispensing of FDA trial drugs under strict protocols, and related clinical and cognitive counseling.
- I am providing you some background information on this issue:
    1. Exhibit A discusses the anticompetitive effects of AWP laws.
    2. Exhibit B discusses a CMS analysis that specialty pharmacies will save consumers $250 billion over the 10 year period 2015-2024.
    3. Exhibit C is a white paper on specialty pharmacy and why it does not translate to brick and mortar pharmacies.
    4. Exhibit D, MN Fiscal Note, p. 1 of 16. Why is there not a fiscal note on this bill? The costs associated with this can be substantial. 2 years ago, Minnesota had a similar bill. The fiscal note in that state was substantial and the bill was defeated.

- The legislation would hamper plan sponsors' abilities to create and utilize unique networks of highly qualified pharmacies to dispense specialty drugs, because it would open specialty services to all pharmacies licensed in the state, even those without specialty accreditation.

- By requiring employers and plans to allow the dispensing of specialty drugs at *any* pharmacy, this legislation threatens patient access to the specialized care and expertise that specialty pharmacies provide through their teams of professionals trained to manage the conditions of these highly specialized patient populations.

- Finally paragraph (2), lines 18-21 on page 1, is also objectionable. While not relating to specialty pharmacy services, this paragraph would dictate contract terms between private market entities. PBM clients are sophisticated purchasers that customize their pharmacy benefits, and corresponding contracts, to their needs. If a client wants this type of information included in their contract, they can simply negotiate for this information. This language would hamstring their freedom of contract.

- For the aforementioned reasons, we urge a Do Not Pass. I will try to answer any questions you have.

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Legal Backgrounder

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THE ANTI-COMPETITIVE EFFECTS OF "ANY WILLING PROVIDER" LAWS

by
Professors Jonathan Klick and Joshua D. Wright

This analysis evaluates the antitrust law ramifications of proposals requiring pharmacy benefit managers ("PBMs") to open up their networks to "any willing provider" meeting the same terms and conditions as other network members. Providers which have failed to meet a PBM's terms have frequently sought the enactment of any-willing-provider ("AWP") legislation (or comparable administrative action). A recent federal proposal, The Pharmacy Competition and Consumer Choice Act of 2011 ("the Act")[1]—provides a useful model for this analysis. Both economic analysis and available empirical evidence suggest the bill will harm consumers by restricting competition.

PBMs work with pharmaceutical manufacturers, retail pharmacies, and health plan sponsors to facilitate agreements among them that efficiently provide consumers with prescription-drug access at a lower cost than would be available otherwise. The Federal Trade Commission ("FTC") described them as "an important development in providing consumer access to prescription drugs." DOJ & FTC, IMPROVING HEALTH CARE: A DOSE OF COMPETITION, ch. 7, at 11 (2004). PBMs now play an integral role in the provision of prescription drugs to insured consumers.

PBMs help to obtain the best prices for consumers by negotiating with pharmaceutical manufacturers on behalf of plan sponsors. *Id.* They obtain discounts from pharmaceutical manufacturers because they have the ability to provide volume purchases of the manufacturers' prescription drugs. PBMs also administer pharmacy benefit services by acting as liaisons between health insurers and pharmacies. For example, when a patient fills a prescription at a retail pharmacy, the pharmacy transmits the patient's insurance information to a PBM, which then verifies the patient's coverage and copayment amount as well as the reimbursement the PBM and the pharmacy have negotiated. *Id.* The PBM transmits this information to the pharmacy, and separately bills the insurer. PBMs in this way serve to facilitate efficient exchange, reduce costs, and ensure payment to pharmacies.

PBMs also facilitate administration of pharmacy services on behalf of health plan sponsors. *Id.* When a retail pharmacy enters into an agreement with a PBM, it joins a network the PBM has created. Many networks are highly exclusive. The greater a network's exclusivity, the more customers a member pharmacy can expect. The prospect of a large number of customers creates intense competition for exclusive networks; this competition leads pharmacies bidding for network membership to offer higher discounts in order to join the network.[2] It is well understood that cost savings resulting from this exclusivity are generally passed on to consumers in the form of lower premiums, lower out-of-pocket costs, and better services.[3]

Jonathan Klick is a professor at the University of Pennsylvania School of Law. **Joshua D. Wright** is a professor at George Mason University School of Law. ***The views expressed here are those of the authors and do not necessarily reflect those of the Washington Legal Foundation. They should not be construed as an attempt to aid or hinder the passage of legislation.***

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Despite the intense competition created by bidding for network membership, the exclusivity of PBMs' networks raises questions about whether consumers have sufficient choices when looking for pharmacies to fill their prescriptions. Additionally, critics make issue of smaller independent pharmacies' inability to join networks.[4] To combat the impact of exclusive networks on independent pharmacies, the same critics propose adoption of AWP laws. Such laws require PBMs to open their networks to any health care providers, including pharmacies, willing to accept the terms of a given plan. *See* Letter from FTC Staff to Sen. James L. Seward, N.Y. Senate 2 (Aug. 8, 2011). Proponents of AWP legislation argue consumers benefit from prohibiting selective or exclusive networks in the form of increased choice, decreased costs, and higher quality service.[5] In addition to the consumer benefits, proponents claim AWP legislation levels the competitive playing field by giving independent community pharmacies the opportunity to compete with larger pharmacies.[6]

The FTC and the Department of Justice ("DOJ") have extensive experience in assessing competition in the health care industry. The agencies held hearings on the issue in 2003,[7] including a panel discussion of the competitive issues surrounding PBMs. Following the hearings, the FTC and DOJ jointly issued a report discussing their findings. *See* DOJ & FTC, *supra*. The agencies concluded AWP legislation is likely to harm consumers because it makes negotiating discounts more difficult for health insurers and restricts their ability to structure plans with different offerings that respond to differences in consumer demand.[8]

Until recently, the pursuit of AWP laws has been limited to state legislatures, but proponents have expanded their efforts to include a national solution. Specifically, the Pharmacy Competition and Consumer Choice Act of 2011 includes a typical AWP provision prohibiting PBMs from "exclud[ing] an otherwise qualified pharmacist or pharmacy from participation in a particular network provided that the pharmacist or pharmacy . . . accepts the terms, conditions and reimbursement rates of the PBM . . ."[9] As with state AWP proposals, the Act could lead to higher health care costs for consumers with no countervailing benefits. As a result, it is likely to decrease consumer choice and reduce access to high-quality, affordable health care for many consumers despite the Act's goals of preserving patient choice and restoring competition in pharmacy services.[10]

The Economics of AWP Laws

Economic Analysis Suggests AWP Laws Hinder Competition. AWP laws prohibit PBMs from selective and exclusive network contracting, thereby reducing both the incentive and the ability of health care providers to vigorously compete with each other to provide the highest quality, lowest cost goods and services. Many providers rely upon the exclusivity of their networks to bring them the highest volume of consumers possible. The prospect of a large consumer base gives providers the incentive to bid aggressively to join exclusive networks. Letter to Rep. McHenry, supra note 8, at 11.

This competition-enhancing effect of exclusive networks is well documented in the economics literature.[11] As the FTC has explained, "Many pharmacies trade higher customer volume for lower prices by offering deeper discounts to PBMs as the exclusivity of the network increases." Letter to Rep. McHenry, *supra*, at 11. Under AWP laws, providers know they cannot be turned away, do not face a significant loss of customers, and therefore have a reduced incentive to offer PBMs the most competitive terms.[12] That reduction in competition harms consumers. Further, opening networks to any willing provider reduces the magnitude of sales providers can expect. Letter from FTC Staff to Rep. Terry G. Kilgore, Va. House of Delegates 10 (Oct. 2, 2006). Thus, they cannot expect to maintain the same economies of scale as with contracts that promise high-volume sales, and they cannot offer the same discounts as they would with more exclusive agreements. Letter to Attorney Gen. Lynch, *supra*, at 4.

AWP laws significantly reduce providers' incentive to engage in price competition. Absent AWP requirements, providers compete to successfully negotiate contracts that maximize their benefits. However, if AWP rules apply, a provider's competitive efforts will allow the same terms to be made available to its competitors without the same investment. This reduces the incentive to invest in innovative, competitive proposals from the outset. Letter to Rep. Kilgore, *supra*, at 11. Such reduced competition is likely to lead to "the suppression of efficient service networks, not the expansion of real consumer choice." *Id.*

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As the FTC explained, AWP laws "preempt competition among providers, instead of protecting the interest of patients. In other words, such laws appear to protect competitors, not competition or consumers." Letter to Attorney Gen. Lynch, *supra* note 8, at 6 (internal footnote omitted). AWP laws do not foster competition; rather, they hinder an important part of the competitive process by prohibiting selective and exclusive contracts that increase providers' incentives to compete, reduce costs, and generate significant benefits for consumers.

Empirical Evidence Regarding Any Willing Provider Laws. Empirical evidence supports the claim that AWP laws have anticompetitive effects. Empirical studies on the topic in peer reviewed journals suggest that AWP laws are associated with higher per capita spending, as predicted by theoretical models in which these laws limit the ability of insurers to secure better prices from providers while incurring higher transactions costs.

The first study, by Michael Vita, examines total per capita health expenditures, as well as per capita hospital and physician expenditures for the period 1983-1997. It shows, after controlling for differential baseline spending levels and time trends across states, that per capita health spending is more than one percent greater in states after they pass stringent AWP laws relative to their baseline spending levels and compared to states with no such laws. These results are robust to the inclusion of a variety of variables, including demographic and economic controls. These effects are above and beyond any increase in spending these laws create by reducing the penetration rate of managed care in a state.[13] Although there are some concerns that the passage of AWP laws may be a reaction to healthcare spending rather than a result of it, exploration of pre-existing trends does not suggest this possibility is driving the effect Vita identified.

An even more relevant study is provided by Christine Piette Durrance, who focuses on pharmacy-specific AWP laws. Christine Piette Durrance, *The Impact of Pharmacy-Specific Any-Willing-Provider Legislation on Prescription Drug Expenditures*, 37 ATLANTIC ECON. J. 409 (2009). This study adopts state of the art panel data methods to isolate the change in spending associated with the passage of AWP laws over the period 1988-1998. Durrance differentiates between laws that do and do not apply to pharmacies, finding that state per capita spending on pharmaceuticals is more than six percent higher when states pass pharmacy-specific AWP laws as compared to states not passing these laws. Further, she finds that total per capita health spending is more than four percent higher. These effects are statistically significant and practically large. Examination of the presence of pre-existing trends suggests that these effects are indeed causal and are not driven by the possibility that AWP laws respond to increased spending.

The empirical research on the topic consistently indicates that AWP laws increase per capita healthcare spending generally and pharmaceutical expenditures in particular directly. The related literature on the effect of these laws on HMO penetration also suggests these laws may increase spending indirectly given that the laws lead to lower penetration and HMOs control costs better than indemnity insurance plans. These results are consistent with economic theory regarding selective contracting.

The FTC and DOJ's conclusions from the healthcare hearings are consistent with the empirical evidence. Furthermore, in their joint report, they found PBMs have contributed substantially to providing consumers with access to prescription drugs. DOJ & FTC, *supra*, ch. 7 at 11. This finding is supported by empirical evidence suggesting that consumers with prescription drug service administered by PBMs save considerably more on drug costs than consumers who pay cash. *Id*. For these reasons, the FTC has been persistent in its efforts to educate states concerning the likely anticompetitive effects arising from AWP legislation. *See* discussion *supra* note 8.

Conclusion

AWP laws at the state and federal level likely lead to less competition and higher prices for consumers while providing no compensating benefits. Selective and exclusive network contracting is a fundamental part of the competitive process which leads to minimizing cost and maximizing consumer welfare. Advocates of AWP proposals understandably seek greater consumer choice and competition among health care providers; however, AWP laws amount to intervention in a competitive process by prohibiting efficient contracting and will ultimately be counterproductive to those goals.

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ENDNOTES

[1] H.R. 1971, 112th Cong. (2011); S. 1058, 112th Cong. (2011). We will refer to both of proposals collectively as "the Act" throughout unless discussing an aspect of bill that does not apply to the other.

[2] *See generally* Kenneth G. Elzinga & David E. Mills, *The Distribution and Pricing of Prescription Drugs*, 4 INT'L J. ECON. BUS. 287 (1997) (explaining the competition-enhancing effects of exclusive provision of prescription drugs); Benjamin Klein & Kevin M. Murphy, *Exclusive Dealing Intensifies Competition for Distribution*, 75 ANTITRUST L.J. 433 (2008) (explaining the competition-enhancing effects of exclusive dealing generally).

[3] Deborah Platt Majoras, Chairman, Fed. Trade Comm'n, Current Topics in Antitrust Economics and Competition Policy 12 (Feb. 8, 2005).

[4] A group of community pharmacies participating in the Medicare prescription drug benefit program has raised this issue in a recently filed complaint in the Eastern District of North Carolina. The pharmacies allege a regulation issued by the U.S. Department of Health and Human Services allowing establishment of "preferred" pharmacies that offer lower copayments and coinsurance than "non-preferred" pharmacies violates Medicare Part D's "any willing provider" provision. Complaint, *Farmville Discount Drug, Inc. v. Sebelius*, No. 5:12-cv-00097-D (E.D.N.C. Feb. 28, 2012). It should be noted that the complaint focuses upon the harm the preferred plans cause to community pharmacies. *Id.* ¶¶ 1, 31, 35. These concerns, of course, are about the welfare of particular small rivals and not about competition or consumer welfare. In fact, smaller competitors are complaining about the more competitive environment resulting from a rule that allegedly circumvents an "any willing provider" requirement.

[5] *See* Letter from David A. Balto to Andrew M. Cuomo, Governor, New York 3 (Oct. 17, 2011); *see also McMorris Rodgers Introduces Pharmacy Competition and Consumer Choice Act*, U.S. HOUSE OF REPRESENTATIVES, (May 24, 2011) (explaining Representative Cathy McMorris Rodgers's expectations that a proposed law will "protect America's community pharmacists and lower costs for their consumers").

[6] *See Community Pharmacists Endorse Bipartisan Pharmacy Competition and Consumer Choice Act*, NAT'L CMTY. PHARMACISTS ASS'N (May 24, 2011).

[7] *See Competition in the Health Care Marketplace*, FED. TRADE COMM'N (last updated July 8, 2009) (providing an overview of the hearings and links to the agenda, materials, and press releases related to them).

[8] *Id.* ch. 6, at 30. In 2005, the FTC advised Representative Patrick T. McHenry of North Carolina that the state's proposed bill, which included an AWP provision, was "likely to limit a PBM's ability to reduce the cost of prescription drugs without providing consumers any additional protections." Letter from FTC Staff to Rep. Patrick T. McHenry, N.C., U.S. House of Representatives 14 (July 15, 2005). In its letter to Rhode Island, the FTC advised that the state's AWP provisions would very likely harm consumers by decreasing access to pharmaceutical services. Letter from FTC Staff to Attorney Gen. Patrick C. Lynch, R.I. 7 (Apr. 8, 2004). Notably, the FTC indicated that the competitiveness of the market made the bills unnecessary because it was unlikely that the limitations on choice made access to pharmacy services inadequate. *Id.* at 5.

[9] H.R. 1971, 112th Cong. § 2 (2011); S. 1058, 112th Cong. § 2 (2011).

[10] *See* Cathy McMorris Rodgers & Anthony Weiner, *McMorris Rodgers and Weiner: Local Pharmacies Play Essential Role in Care*, ROLL CALL (June 6, 2011, midnight).

[11] *See, e.g.*, Elzinga & Mills, *supra* note 2, at 297 ("[F]or third-party payers, and consumers of prescription drugs under their coverage, intervention by . . . PBMs is unambiguously beneficial . . . ."); Klein & Murphy, *supra* note 2.

[12] *See* Letter to Rep. McHenry at 11 n.44; Letter to Attorney Gen. Lynch, *supra* note 8 at 5 ("From the perspective of a pharmacy negotiating the terms on which it is willing to deal with health insurers and employee benefit plans, this means that a pharmacy . . . faces no threat of sales losses if it fails to bid aggressively for inclusion in the payers' networks.").

[13] Numerous studies agree that managed care penetration reduces health care spending. On this point, see, for example, Gaskin and Hadley, *The Impact of HMO Penetration on the Rate of Hospital Cost Inflation, 1985-1993*, 34 INQUIRY 205 (1997) and Glenn Melnick et al, *Managed Care, Competition, and Hospital Cost Growth in the U.S., 1986-1993* (RAND Working Paper, 1997). Michael A. Morrisey & Robert L. Ohsfeldt, *Do "Any Willing Provider" and "Freedom of Choice" Laws Affect HMO Market Share?*, 40 INQUIRY 362 (2003), among other studies show that restrictions on selective contracting reduce managed care penetration rates. Taken together, these studies suggest that any willing provider laws can have two effects on healthcare spending: (1) the direct effects discussed in the text above, and (2) indirect effects through a reduction in managed care participation as suggested in this footnote.

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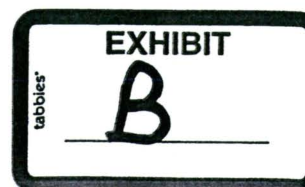
Mail-Service and Specialty Pharmacies Will Save More than $300 Billion for Consumers, Employers, and Other Payers Over the Next 10 Years

Prepared for

September 2014



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I. Executive Summary

On healthcare issues, poll after poll shows that cost is the greatest concern for both consumers and employers. At the same time, the growth of Amazon.com and other online retailers highlights greater consumer demand for convenience and home delivery. With prescription drugs, these trends have led to greater use of high-tech mail-service pharmacies. While patients with short-term, acute needs continue to use drugstores, patients with chronic conditions like high blood pressure increasingly rely on mail-service pharmacies to save money and get prescriptions delivered directly to their homes.

Trends in pharmaceutical development have also led to the creation of specialty pharmacies. Specialty pharmacies are distinct from traditional pharmacies in that they coordinate many aspects of patient care and disease management for patients on complex, high-cost drug therapies for rare diseases. They efficiently deliver medications with special handling and storage or distribution requirements. They also coordinate care with other clinicians and health care professionals to improve clinical and economic outcomes for patients and payers. Conventional pharmacies are not equipped to fulfill this range of needed services, so payers and benefit managers turn to the unique expertise of specialty pharmacies.

Proposed state laws and regulations that restrict mail-service and specialty pharmacy options threaten to raise costs for both consumers and payers.

Major Findings

Compared to brick-and-mortar drugstores, mail-service and specialty pharmacies offer deeper discounts and enhanced services. Based on Visante's analysis, this generates substantial savings for the U.S. health care system:

- Mail-service pharmacies will save an estimated **$5.1 billion** for consumers, employers, and other payers in 2015, and **$59.6 billion** over the 10-year period 2015-24.
- Specialty pharmacies will save an estimated **$13.5 billion** for consumers, employers, and other payers in 2015, and **$251.5 billion** over the 10-year period 2015-24.
- Combined, mail-service and specialty pharmacies will save an estimated **$18.6 billion** for consumers, employers, and other payers in 2015, and **$311 billion** over the 10-year period 2015-24.

The major findings above are based on a recent analysis by the Centers for Medicare & Medicaid Services (CMS) that found that mail-service pharmacies save an average of 16% on prescription costs compared to retail pharmacies. Proposed legislation could threaten the ability of mail-service pharmacies to continue to provide such savings. Likewise, specialty pharmacies have demonstrated average savings of 10% on drug costs and substantial savings on non-drug medical costs compared to retail pharmacies. Legislation that restricts the use of specialty pharmacies could put these savings at risk.

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II. Discussion

Use of Mail-Service Pharmacies for Chronic Care Prescriptions

Mail-service pharmacies typically provide 90-day prescriptions for medications that consumers need on an ongoing basis. Local drugstores are used for new therapy starts and acute-care prescriptions. Consumers use mail-service pharmacies once they are stabilized on a medication, after having finished several 30-day prescriptions from their local drugstores.

Mail-Service Pharmacies Encourage Generic Drug Use

Without patients waiting in line at the pharmacy counter, mail-service pharmacists have more "fill-to-receive" time that allows them to contact patients and physicians to seek approval for the substitution of generic drugs when brands are prescribed. As a result, the generic substitution rate (GSR), which measures how often generics are substituted for brands when a generic is available, is higher for mail-service pharmacies than drugstores.[1,2] Another measure, the generic dispensing rate (GDR), measures the proportion of all dispensed prescriptions that are generic. Comparisons between mail-service pharmacy and drugstore GDRs must account for the different mix of drugs, prescription sizes, and copay incentives for each channel.[3] When these differences are taken into account, GDRs are comparable for mail-service pharmacies and drugstores.

What Makes Mail-Service Pharmacies More Efficient

Mail-service pharmacies are able to generate savings for consumers and payers by being vastly more efficient than brick-and-mortar drugstores. Through the use of computer-controlled quality processes, robotic dispensing machinery, and advanced workflow practices, mail-service pharmacies are able to fill large quantities of prescriptions while enhancing quality and reducing costs. This technology allows pharmacists to focus on clinical and cost management functions, rather than counting pills, printing instructions, and assembling prescriptions by hand as is done in drugstores.

Superior Safety through Mail-Service Pharmacies

Technologically advanced mail-service pharmacies achieve dispensing accuracy rates up to 23 times better than drugstores. Studies have found an error rate of nearly one in every 50 prescriptions (1.72%) filled at drugstores, compared to less than one in every 1,000 prescriptions (0.075%) at mail-service pharmacies.[4] By being more accurate, mail-service pharmacies help ensure that patients get the correct drugs, dosages, and dosage forms, and thus avoid costly adverse drug events that can result in hospitalization.

Patients Have Access to 24/7 Counseling and Support

Mail-service pharmacies provide patients convenient access to 24/7 confidential counseling and answers to questions on prescription medications over the phone or Internet. Pharmacists also

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[1] Federal Trade Commission, "Pharmacy Benefit Managers: Ownership of Mail-Service Pharmacies," August 2005.
[2] Wosinska, M., et al., "Generic Dispensing and Substitution in Mail and Retail Pharmacies," *Health Affairs*, July 2004.
[3] Federal Trade Commission, op. cit.
[4] Teagarden, J.R., et al., "Dispensing Error Rate in a Highly Automated Mail-Service Pharmacy Practice," *Pharmacotherapy*, November 2005.

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counsel patients on affordable medication options and identify generic and therapeutic substitution opportunities.

Mail-Service Pharmacies Improve Patient Adherence

Patients receiving their prescriptions through mail-service pharmacies follow their doctors' prescribed drug regimens more often than drugstore users. This improves health outcomes and often reduces non-drug medical costs, such as hospitalizations. Part of the reason mail-service pharmacy improves adherence is that patients receive their prescriptions in 90-day supplies, rather than 30-day supplies, which tends to reduce adherence problems.[5] Even after accounting for 90-day prescriptions, however, evidence suggests that mail-service pharmacy users achieve higher adherence rates than drugstore users.[6] For patients with chronic conditions, such as diabetes, high cholesterol, and high blood pressure, studies find adherence is approximately eight percentage points higher for mail-service pharmacy users.[7,8,9] Lower copays, home delivery, and refill reminder programs all likely play roles.

Less Waste at Mail-Service Pharmacies

Prescriptions obtained through mail-service pharmacies are associated with less waste than 90-day prescriptions obtained through drugstores. Waste occurs when patients stop taking their medication before using the entire supply of a prescription. This can be due to the need to discontinue therapy, switch to a different drug, or change dosage strengths. To minimize waste, mail-service pharmacies are typically used only once a patient is stable on a medication after having finished several 30-day prescriptions from their local drugstores. A 2011 study of patients taking statin medications found that on a yearly basis, four 90-day drug prescriptions through drugstores were associated with 4.04 days of waste, while four 90-day mail-service prescriptions were associated with 3.08 days of waste.[10]

Advantages of Specialty Pharmacies

Specialty pharmacies are also widely utilized by pharmacy benefit managers (PBMs), health insurance companies, and plan sponsors to help manage prescription drug costs and improve quality of care. Based on Visante's analysis, specialty pharmacy management delivers three major advantages:

- *Helps Patients Take Complex Medications Safely and Effectively:* Specialty pharmacies employ highly trained teams of patient care coordinators, pharmacists, nurses, and insurance specialists, all working toward helping patients take complex medications safely and effectively. Specialty pharmacy services significantly improve the quality of patient care relative to other distribution channels.

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[5] Hermes M., et al., "Adherence to Chronic Medication Therapy Associated with 90-Day Supplies Compared with 30-Day Supplies," *Journal of Managed Care Pharmacy*, 2010, 16:141-142.

[6] Duru, K., et al., "Mail-Order Pharmacy Use and Adherence to Diabetes-Related Medications," *The American Journal of Managed Care*, January, 2010.

[7] Ibid.

[8] Zhang, L., et al., "Mail-Order Pharmacy Use and Medication Adherence among Medicare Part D Beneficiaries with Diabetes," *Journal of Medical Economics*, October 2011.

[9] Devine, S., et al., "A Comparison of Diabetes Medication Adherence and Healthcare Costs in Patients Using Mail Order Pharmacy and Retail Pharmacy," *Journal of Medical Economics*, 2010.

[10] Vuong, T., et al., "Statin Waste Associated with 90-day Supplies Compared to 30-day Supplies," Prime Therapeutics, 2011.

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- *Decreases Drug Costs by 7-12%:* Specialty pharmacies and coordinated benefit management strategies provide a savings advantage of 7-12% relative to other distribution channels such as retail pharmacies and physician offices.
- *Decreases Non-Drug Medical Costs by 10-40%:* Specialty pharmacy services reduce expenditures on hospitalizations and other medical costs through a range of patient-centered services that enhance patient adherence to drug therapies, including patient education, training and monitoring, nursing and supportive care, case management, and 24/7 pharmacy support.

Specialty Pharmacies Must Meet Strict Requirements

Specialty pharmacies must meet many requirements to effectively handle injectable biologic medications that require refrigeration and can cost many thousands of dollars per dose. These requirements include:

- Providing round-the-clock access to pharmacists, nurses, and clinicians dedicated to and specially trained with respect to the disease state treated by the drug, the specialty drug itself, and the drug's potential side effects
- Adhering to rigorous storage, shipping, and handling standards to meet product-label shipping requirements, such as temperature control, and timely deliveries of the product in optimal condition
- Performing disease-specific and drug-specific patient care management services that meet the unique needs of each patient and that incorporate multiple safeguards when dispensing and delivering the drug to ensure patient safety
- Collecting data and tracking outcomes for specific patients as required
- Managing compliance and persistency of drug regimens for patients
- Managing care within manufacturer Risk Evaluation and Mitigation strategies (REMS) program requirements, including REMS reporting, Phase IV trials, the dispensing of FDA trial drugs under strict protocols, and related clinical and cognitive counseling

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III. Savings from Mail-Service and Specialty Pharmacies

Visante projects 10-year savings (2015-24) for consumers, employers, and other payers of $311 billion, based on mail-service savings of $59.6 billion and specialty savings of $251.5 billion. Estimated savings in 2015 will be $5.1 billion for mail-service and $13.5 billion for specialty.

Estimated mail-service pharmacy savings are based on a recent cost analysis conducted by CMS that compared prescription costs at mail-service pharmacies to costs at brick-and-mortar drug stores in Medicare Part D. The agency found that costs at mail-service pharmacies were 16% less than drug stores across all drugs examined.[11] Many studies have also shown improved patient adherence to prescription regimens with mail-service pharmacies. [12,13,14,15]

Specialty pharmacies also deliver significant savings. For example, the Pennsylvania Medicaid program's use of specialty pharmacies helped save 21% on overall health expenditures for beneficiaries using specialty drugs, including 12% on specialty drug costs and 56% on inpatient hospital costs.[16] Other studies have demonstrated that specialty pharmacies save 13-23% on drug costs. [17, 18] In addition, specialty pharmacies have demonstrated significantly improved patient adherence and reduced medical costs for transplant patients, patients with HIV, hepatitis C, cancer and multiple sclerosis. [19, 20, 21, 22, 23, 24, 25]

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[11] Centers for Medicare & Medicaid Services, "Part D Claims Analysis: Negotiated Pricing Between General Mail Order and Retail Pharmacies," December 2013, available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Negotiated-Pricing-Between-General-Mail-Order-and-Retail-PharmaciesDec92013.pdf

[12] Schmittdiel et al., "Safety and Effectiveness of Mail Order Pharmacy Use in Diabetes," *American Journal of Managed Care*, 2013; 19(11):882-887.

[13] Zhang, L et al., "Mail-Order Pharmacy Use and Medication Adherence among Medicare Part D Beneficiaries with Diabetes," *Journal of Medical Economics*, October 2011.

[14] Hermes M., et al., "Adherence to Chronic Medication Therapy Associated with 90-Day Supplies Compared with 30-Day Supplies," *Journal of Managed Care Pharmacy*, 2010, 16:141-142.

[15] Duru, K., et al., "Mail-Order Pharmacy Use and Adherence to Diabetes-Related Medications," *The American Journal of Managed Care*, January, 2010.

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[17] Medco Health Solutions, "Specialty Pharmacy: Future Evolution of Service and Value," Presented at PCMA Specialty Pharmacy Symposium, May 2008.

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[19] Miller S., "Personalizing the Specialty Business," Presentation at the PCMA Specialty Pharmacy Business Forum," April 2012.

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[21] Tang. J., and Faris, R., "Exploring the Impact of Dispensing Channel on Medication Adherence Among Multiple Sclerosis Patients," Presented at the 14th Annual International Meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), May 2009.

[22] Mitra, et al., "Treatment Patterns and Adherence among Patients with Chronic Hepatitis C Virus in a US Managed Care Population," *Value Health*, Jun-Jul, 2010; 13(4):479-86.

[23] Tan, et al., "Impact of Adherence to Disease-Modifying Therapies on Clinical and Economic Outcomes among Patients with Multiple Sclerosis," *Advances in Therapy*, Jan 2011; 28(1):51-61.

[24] Tschida, et al., "Outcomes of a Specialty Pharmacy Program for Oral Oncology Medications," *American Journal of Pharmacy Benefits*, 2012;4(4):165-174.

[25] Tschida, et al., "Managing Specialty Medication Services Through a Specialty Pharmacy Program: The Case of Oral Renal Transplant Immunosuppressant Medications," *Journal of Managed Care Pharmacy*, 2013; 19(1):26-41

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Cost of Pharmacy Restrictions

Savings through mail-service and specialty pharmacies will only be available if the legal and regulatory environment remains neutral toward such pharmacies. When state or federal laws or regulations place restrictions or prohibitions on the use of these pharmacies, savings are threatened.

Health plans, insurers, and PBMs typically use a variety of incentives to encourage their enrollees to use mail-service pharmacies, especially for maintenance medications. Legislation that prohibits plans from using automatic home delivery of 90-day refills for chronic medications limits the use of the lowest-cost pharmacy channel option.

A study by the Maryland Health Care and Insurance Commissions found that anti-mail service legislation can lead to dramatically lower mail-service pharmacy use. In Maryland, mail-service pharmacies accounted for just 7% of prescription drug payments for employer plans subject to the legislation. This compares with mail-service accounting for 22% of payments for self-insured employer plans not subject to the legislation.[26] In short, anti-mail-service legislation cut the use of mail-service pharmacies by more than 50%, which means that any resulting savings was also cut by more than 50%.

Based on this experience, state or federal laws or regulations that place restrictions or prohibitions on the use of mail-service and/or specialty pharmacies could substantially increase prescription drug costs.

[26] Note that the Maryland study's finding that mail-service pharmacies accounted for 22% of prescription drug payments is consistent with the national mail-service penetration rate of approximately 7% of prescriptions, since mail-service prescriptions are typically three times larger than retail prescriptions (90-day vs. 30-day supply). In addition, the chronic care medications dispensed by mail-service pharmacies are not available generically as often as acute care medications dispensed by drugstores. This also makes mail-service pharmacies' share of payments marginally greater than their share of prescriptions.

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IV. Methodology and Savings Estimates

The following important assumptions were incorporated into the analysis:

1. Total U.S. outpatient prescription drug expenditures for 2015-24 are projected to be $3.9 trillion ($295 billion in 2015),[27] with $2.66 trillion for traditional (non-specialty) prescription drugs ($227 billion in 2015) and $1.26 trillion for specialty medications dispensed by pharmacies within prescription benefit plans ($68 billion in 2015).[28]
2. Projected expenditures for specialty medications above capture only the approximate 50% of specialty expenditures that flow through the pharmacy benefit (i.e., potentially available for pharmacies). The other 50% flow through the medical benefit (i.e., physician offices, clinics, hospitals).[29] For purposes of this analysis, our savings estimates include only the drug expenditures within prescription benefit plans.
3. 14% of traditional outpatient drug expenditures flows through mail-service pharmacies.[30]
4. CMS found that mail-service pharmacies save 16% vs. retail pharmacies[31]
5. Visante estimates that specialty pharmacies save 10% of specialty drug costs vs. retail pharmacies, plus an equal amount of "non-drug medical/hospital cost savings." [32]
6. Appendix A estimates savings for each state.[33]

Methodology: Mail-Service/Specialty Pharmacy Savings

	Projected Expenditures 2015-24	*billions $*					
		Traditional Rx Benefit	**Specialty Rx Benefit**	**Total Outpatient Rx Benefit**	**Specialty Med Benefit**	**Total Specialty**	**Source**
1	Total US Spend for Outpatient Prescription Drugs Dispensed Under the Pharmacy Benefit			$3,917			CMS National Health Expenditures (NHE), Prescription Drugs, Projected
2	Specialty spend approx $80b in 2011, plus approx 14% annual increases.					$2,515	Visante estimates based on published data from IMS Health and PBM Drug Trend Reports
3	50% of specialty drug spend goes through Rx benefit (is incl in NHE Rx), plus 50% through medical benefit (is not incl in NHE Rx)	$2,660	$1,258		$1,258		EMD Serono Specialty Digest, 7th edition
4	14% of traditional drug spend dispensed by mail-service pharmacies	$372					IMS Health, Channel Distribution by Non-Discounted Spending
	Savings from Mail-Service and Specialty						
5	Mail-service pharmacy: Estimated savings of 16%	$59.6					CMS analysis 2013
6	Specialty pharmacy: Estimated savings of 10%		$125.8				Visante estimates based on published studies
7	+ equal amount non-drug medical/hospital savings		$125.8				
8	**Total Savings**	**$59.6**	**$251.5**	**$311.1**			

[27] CMS National Health Expenditures (NHE), Prescription Drugs, Projected, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html
[28] Visante estimate based on published data from IMS Health and PBM Drug Trend Reports.
[29] EMD Serono Specialty Digest™, 7th edition. http://www.specialtydigest.emdserono.com/
[30] IMS Health, Channel Distribution by Non-Discounted Spending (U.S.), available at http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/Press%20Room/2012_U.S/Channel_Distribution_by_Non-Discounted_Spending_U.S.pdf
[31] Centers for Medicare and Medicaid Services, "Part D Claims Analysis: Negotiated Pricing Between General Mail Order and Retail Pharmacies," December 2013, available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Negotiated-Pricing-Between-General-Mail-Order-and-Retail-PharmaciesDec92013.pdf
[32] Visante estimates based on evaluation of more than fifty published studies.
[33] Kaiser Family Foundation, Distribution of Health Care Expenditures by Service by State of Residence, available at http://kff.org/other/state-indicator/health-spending-by-service-2/

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APPENDIX A: Estimated Savings from Mail-Service/Specialty Pharmacies

Based on projected drug expenditures 2015-24 (millions)

State	Mail-Service Pharmacy Savings	Specialty Pharmacy Savings (Rx benefit)	Total Savings
Alabama	$1,128	$4,762	**$5,890**
Alaska	$116	$491	**$607**
Arizona	$1,076	$4,544	**$5,620**
Arkansas	$563	$2,377	**$2,940**
California	$5,890	$24,867	**$30,757**
Colorado	$704	$2,970	**$3,674**
Connecticut	$907	$3,827	**$4,734**
Delaware	$219	$924	**$1,143**
District of Columbia	$110	$466	**$576**
Florida	$4,561	$19,256	**$23,818**
Georgia	$1,733	$7,316	**$9,049**
Hawaii	$262	$1,106	**$1,368**
Idaho	$232	$980	**$1,212**
Illinois	$2,251	$9,502	**$11,753**
Indiana	$1,198	$5,056	**$6,254**
Iowa	$594	$2,507	**$3,101**
Kansas	$471	$1,987	**$2,458**
Kentucky	$852	$3,597	**$4,450**
Louisiana	$996	$4,206	**$5,202**
Maine	$301	$1,272	**$1,573**
Maryland	$1,285	$5,424	**$6,709**
Massachusetts	$1,384	$5,841	**$7,225**
Michigan	$1,840	$7,769	**$9,609**
Minnesota	$969	$4,092	**$5,061**
Mississippi	$568	$2,397	**$2,965**
Missouri	$1,233	$5,204	**$6,436**
Montana	$145	$613	**$758**
Nebraska	$350	$1,478	**$1,828**
Nevada	$479	$2,022	**$2,501**
New Hampshire	$270	$1,141	**$1,411**
New Jersey	$2,069	$8,733	**$10,802**
New Mexico	$323	$1,362	**$1,684**
New York	$4,410	$18,619	**$23,029**
North Carolina	$1,944	$8,208	**$10,153**
North Dakota	$155	$656	**$812**
Ohio	$2,096	$8,847	**$10,943**
Oklahoma	$703	$2,969	**$3,673**
Oregon	$641	$2,707	**$3,348**
Pennsylvania	$2,850	$12,031	**$14,880**
Rhode Island	$264	$1,115	**$1,380**
South Carolina	$877	$3,703	**$4,580**
South Dakota	$126	$534	**$660**
Tennessee	$1,332	$5,623	**$6,955**
Texas	$4,456	$18,814	**$23,270**
Utah	$419	$1,768	**$2,187**
Vermont	$107	$453	**$560**
Virginia	$1,459	$6,159	**$7,618**
Washington	$1,095	$4,621	**$5,716**
West Virginia	$435	$1,836	**$2,271**
Wisconsin	$1,036	$4,372	**$5,408**
Wyoming	$95	$401	**$496**
US Total	**$59,578**	**$251,527**	**$311,105**

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Specialty Pharmacy and Networks

As the number and range of specialty drug and biologic products available to patients has increased dramatically in recent years, health plans and payers are increasingly relying on specialty pharmacies to dispense these medications. While their roles are still evolving, specialty pharmacies are distinct from traditional pharmacies because they coordinate many aspects of care for patients with complex, chronic conditions and help patients with rare disorders to manage more effectively their treatment, side effects, and interactions with other therapies. The enactment of any willing pharmacy legislation would greatly damage the ability of specialty pharmacies to continue to provide these valuable services.

Scale and Scope of Services

The medications dispensed by specialty pharmacies differ significantly from the drugs dispensed by traditional pharmacies, because often they require special storage, handling, and packaging prior to dispensing. These products are usually significantly more expensive than conventional medications and require additional controls to minimize waste and assure that patients take them appropriately. Many specialty drugs are dispensed in low volumes and target rare disorders. To take advantage of economies of scale, specialty pharmacies can serve an entire region or the nation using sophisticated information technology and logistics to dispense medications directly to the patient's home via the mail or a common carrier.

Compared with traditional pharmacies, specialty pharmacies generally apply a wider range of clinical skills and offer much more intensive, higher-touch patient services. Specialty pharmacies lead efforts to coordinate patient care with physicians and other health professionals to coordinate to avoid gaps in care and assure that patients are receiving and taking the proper medications. Specialty pharmacies can coordinate a plan of care and determine who will conduct the activities or provide the service, when such activities and services are to occur, and patient-specific transition of care needs. Traditional pharmacies are rarely equipped to provide this array of management and clinical services. Increasingly, the Food and Drug Administration (FDA) requires risk evaluation and mitigation strategies (REMS) for drugs, and manufacturers sometimes prefer to limit distribution of drugs with REMS to specialty pharmacies they know will be able to ensure that the REMS are well implemented.

Quality Standards and Networks

Health plans and pharmacy benefit managers typically contract with selected specialty pharmacies in their pharmacy networks to assure high-quality services, avoid waste, and ensure appropriate use of the medications. URAC, an independent accreditation and certification organization, has established standards for specialty pharmacy such as requiring the provision of:

- Patient management program services based on best available medical or scientific evidence,
- Processes and protocols to effectively communicate to prescribers and other health care providers,
- Assessment of appropriate and inappropriate drugs, including medication reconciliation,
- A plan for providing and coordinating services,
- Continuity of care during all patient transitions (e.g., hospitalization, rehabilitation),
- At-risk patient identification and recruitment to its patient management program, and
- Periodic patient reassessment to assure the patient is adhering to therapy and achieving therapeutic benefits.

By selectively contracting with a limited number of specialty pharmacies to participate in their networks, plan sponsors are able to:

- Improve patient adherence,
- Improve clinical outcomes,
- Reduce inappropriate utilization,
- Reduce product waste,
- Achieve lower unit costs through effective formulary management,
- Negotiate better discounts from manufacturers, and
- Reduce non-drug medical care costs.

Any Willing Pharmacy (AWP) Requirements are Inconsistent with Specialty Pharmacy

Any willing pharmacy (AWP) requirements adopted by several states are not consistent with the rationale for Specialty Pharmacy. AWP laws assume that all pharmacy services are the same, no matter who provides them or how they are organized.

- Specialty Pharmacy is based on a coordinated care model and requires a higher degree of organization, care management, and clinical knowledge about rare disorders and biological products than is available in a traditional pharmacy.
- Further, the medications handled by specialty pharmacies require greater care in packaging and delivery, as well as inventory control, than is typically found in a traditional pharmacy.
- Specialty pharmacies provide clinical support through nurses, in addition to pharmacists, to help patients deal with side effects and questions about treatment. Most retail pharmacies do not offer this level of care.
- Where the FDA has imposed a REMS as a condition of approval, manufacturers may insist on limiting distribution to specialty pharmacies that have proven they can manage the risk mitigation; not every pharmacy can do it.

The reality is that while traditional pharmacies might like to dispense specialty drugs, they are not equipped or able to deliver the clinical management and services that these products require.

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Revised

Consolidated Fiscal Note **2015-2016 Legislative Session**

SF1530 - 1E - "Pharm Freedom of Choice "

Chief Author: **John Hoffman**
Commitee: **State Departments And Veterans Division**
Date Completed: **04/18/2016**
Lead Agency: Human Services Dept
Other Agencies:
Minn Management and Budget Health Dept
MnSure

State Fiscal Impact	Yes	No
Expenditures	X	
Fee/Departmental Earnings		X
Tax Revenue		X
Information Technology		X

Local Fiscal Impact	X	

This table shows direct impact to state government only. Local government impact. if any, is discussed in the narrative.
Reductions shown in the parentheses.

State Cost (Savings)		Biennium		Biennium	
Dollars in Thousands	**FY2015**	**FY2016**	**FY2017**	**FY2018**	**FY2019**
Human Services Dept					
General Fund	-	-	769	2,286	2,401
Health Care Access	-	-	572	1,426	1,553
Minn Management and Budget					
General Fund	-	-	27	62	74
All Other Funds	-	-	13	31	36
State Total					
General Fund	-	-	796	2,348	2,475
Health Care Access	-	-	572	1,426	1,553
All Other Funds	-	-	13	31	36
Total	**-**	**-**	**1,381**	**3,805**	**4,064**
Biennial Total			**1,381**		**7,869**

Full Time Equivalent Positions (FTE)		Biennium		Biennium	
	FY2015	**FY2016**	**FY2017**	**FY2018**	**FY2019**
Human Services Dept					
General Fund	-	-	-	-	-
Health Care Access	-	-	-	-	-
Minn Management and Budget					
General Fund	-	-	-	-	-
All Other Funds	-	-	-	-	-
Total	**-**	**-**	**-**	**-**	**-**

Lead Executive Budget Officer's Comment

I have reviewed this fiscal note for reasonableness of content and consistency with MMB's Fiscal Note policies.

EBO Signature: Ahna Minge Date: 04/18/2016
Phone: 651 259-3690 Email ahna.minge@state.mn.us

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SB 2301 – Specialty Pharmacy Services
Industry Business & Labor Committee
9:30 AM – Tuesday – January 31, 2017 – Roosevelt Room

Chairman Klein, members of the Senate Industry Business & Labor Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here to speak to you today about Senate Bill 2301.

The Board of Pharmacy has been increasingly aware of the term "*specialty drug*" being used in the pharmaceutical market place. We license pharmacies, both in state and out-of-state, and we have noticed an increase in number of out-of-state pharmacies that involve the dispensing of "*specialty*" medications. In its inception, "*specialty drugs or medications*" were thought to be high cost items. Recently that list of "*specialty drugs or medications*" has been extended by many Third Party Payers contracts to include medications that have been in the market place for quite some time. To be fair, there are "*specialty drugs or medications*" with distribution and dispensing limited by the Food & Drug Administration because of higher consideration of patient monitoring that are required due to the extremely complex nature of taking those pharmaceutical products. Many medications included in specialty drug lists by Third Party Payers appear to be products that are available and have been dispensed by pharmacies for several years.

The Board of Pharmacy has heard from the public through complaints in which the individual is concerned about being required to obtain their medications through the mail. The patient is often concerned that these expensive medications maybe subjected to extreme temperatures in the process. Often the person wishes to obtain their medication from their local pharmacy. However, the Third-Party Payer limits the opportunity for their pharmacy to dispense that product to them. This is not typically due to the pharmacy's ability to obtain and dispense the medication, but the Third-Party Payer's preference.

Another growing trend in the market place is to require the pharmacy to submit to an accreditation process devised by the Third-Party Payer to be eligible to dispense to patients of that Third-Party Payer medications deemed "*specialty drugs or medications*".

The North Dakota State Board of Pharmacy has long adhered to the premise that our pharmacists and pharmacies are equally licensed. As long as they have met all the requirements and acquired the appropriate state and federal licenses, they should be allowed to dispense any and all pharmaceutical products set forth in that practice. We strongly believe the patient should decide the pharmacy of their choice.

In summary, the Board of Pharmacy is supportive of defining "*specialty drugs or medications*" and ensuring the patient's access to the pharmacy of their choice.

I will be happy to answer any questions you may have, and do appreciate your time.

Testimony for Public Hearing
Industry, Business, And Labor
January 31, 2017

Danielle McDermott
515 2nd Ave SE
Rugby, ND 58368

S.B. No. 2301 (Industry, Business and Labor) – Specialty Pharmacy

Good Morning Industry, Business and Labor Committee Members. My name is Danielle McDermott and I am from Rugby, ND. I am a pharmacy technician at the Heart of America Medical Center, a Medication Reconciliation Technician and a patient at the Heart of America Clinic Pharmacy and I am in favor of this bill. I have had diabetes for almost 15 years. I have always filled my prescriptions at a pharmacy near my home and have never had any issues with filling my prescriptions until now.

I was attempting to fill my prescription of insulin for a 3 month supply. My pharmacy told me that my insurance company (provided by my husband's employer, General Electric) wouldn't be able to fill my prescription for a 3 month supply and if I had any questions, I was supposed to contact my insurance company.

Upon speaking with my insurance, I was given a few options. My first option was to get my prescriptions filled at a CVS or a Target. I explained to the representative that in ND chain stores are not allowed to have pharmacies in their stores so Target, Wal-Mart and Kmart, etc. were not an option. I also explained that the nearest CVS store was over 70 miles away from my home and driving there to fill my prescriptions was not an option if I needed my medications now. My second option was to utilize their mail order prescription service. I asked why and she explained that there were no other options because my local pharmacy did not have a contract in place to give me a 3 month supply of my medication.

I have several issues with this:

My first concern is it winter in North Dakota and there is no way that my insulin (a liquid) can be delivered to my house and then sit outside in freezing temperatures from the time that it is delivered until the time I get home from work. Mail is usually delivered around 3 pm and there are days when it is 6pm by the time I get off work. Frozen insulin is not effective.

My second concern is that mail order pharmacies are not located in this state. I am a firm believer in supporting the local businesses in my community, and now my insurance company gets to dictate where I can purchase my medication?

My next issue is based on my previous experiences with mail order companies through my job as a pharmacy technician. Prescriptions don't show up on time and they sometimes get lost in the mail. If this would happen to me, I would incur additional expenses in that I would have to go to my local clinic, see a provider to get a new prescription and then I would have to go to my local pharmacy. My pharmacy would then tell me that it is too early to fill and my insurance won't pay for it so I can either, (1.) Pay cash for the insulin (close to $300 a vial) or (2.) I would have to wait and hope my prescription shows up and is not frozen on top of that. This isn't something

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that any patient should have to go through. I want to get my care locally and I shouldn't have to have my insurance company dictate where I fill my prescriptions or where I get my healthcare. Isn't there freedom of choice for all patients?

Another issue that I have with this is that GE (General Electric) uses Caremark. My insurance is a Caremark plan. The entire reason behind me having to go to a CVS is that Caremark owns CVS. GE thinks that they are getting this great deal with lower costs of the plan but then CVS is turning around and making their patients go through a mail order pharmacy. There should be some kind of regulation because insurance companies are dictating where you have to get your medications and in my opinion this is the patient's choice. If I wanted to get my prescriptions at a local pharmacy then I should get to choose the pharmacy that is literally a couple blocks from my house.

The next issue that I want to discuss is the fact that when a mail order pharmacy doesn't end up getting medications out in time for the patient, where am I going to have to go to get medication to get me by until my prescription shows up? I will have to go to my local pharmacy. When I have questions or concerns about my prescription or medication who am I going to go and talk to? When I want to talk to a pharmacist about other options for medications, who am I going to call? It is going to be my local pharmacy. I do not want to have to sit on hold for a half hour to an hour just waiting to speak to a representative. Then when I am finally able to speak to a representative, they will not be a pharmacist and will not even be able to answer my questions. Can I rely on the information that I am receiving from a "representative?"

Mail order pharmacies should be a last resort option, not a first alternative choice. They take the money out of small North Dakota communities that need the money. Rugby is one of these small towns and without money/support from the local residents; our town will simply not survive. It is very unfair to make the patients spend their money elsewhere when the care is in our town. I shouldn't have to go through these issues when filling my prescriptions and I should be able to get a 3 month supply of my medications when I want.

Local care is the way that healthcare should be. At my job, I see this all the time; Elderly people have a hard time understanding and hearing over the phone especially if they have to call and talk to someone over an automated system. Imagine an 80 year old having to make a phone call, punch in their ID number and information that is needed, and then understand what the person is trying to tell them, including that maybe their medication was already sent out in the mail, but they can go online to track the shipment. If this person is having a hard time hearing the person or automated system, how is this patient going to get help? They will have to come into the local pharmacy and ask for help. What if this medication was urgent, now that elderly person needs to wait to receive it?

Mail order pharmacies are taking away from local health care. We need that local health care available and if mail order pharmacies don't have rules and regulations in place, they will close up every local pharmacy in our state. We are able to have local care with our providers so why should pharmacy be any different.

On a side note, CVS Caremark plan does cover a 3 month's supply of certain medications, including birth control. There is no acceptable reason that insulin, test strips and other medications, whether it be for blood pressure, diabetes, cholesterol or more serious medications

like blood thinners, be sent in the mail with the potential of getting lost, freezing, being miss-delivered or simply not being received when needed.

Because of the issues and reasons that I have stated, I feel that we need to regulate specialty pharmacies. If we allow specialty pharmacies into our state, healthcare will slowly go away from local care. Local Care is what we need in a society when you are dealing with individuals that have complex medication regimens.

Please support this bill to regulate the specialty pharmacies.

Thank you for giving me the opportunity to speak to you all today

Sincerely,

Danielle McDermott

Danielle McDermott

Testimony for Public Hearing
Industry, Business, and Labor
January 31, 2017
Tallie Schneider

S.B. No. 2301 (Industry, Business, and Labor) – Specialty Pharmacy

My husband and I have struggled with infertility since we decided we wanted a baby after we got married in June 2008. The first couple years we didn't really stress over it since I was still finishing up my college degree. We somehow conceived without medical intervention the summer of 2011, after 3 years of not preventing a pregnancy. The pregnancy resulted in the birth of our only child, a boy named Camden, in April 2012. After Camden turned 1 year old we decided to no longer prevent pregnancy again the summer of 2013, knowing that it had taken us some time to conceive Camden. I used at home ovulation kits to help determine ovulation and we became pregnant again around March 2014, just shy of trying for a year. At 8 weeks pregnant I began spotting so I went in for an ultrasound and a heartbeat was confirmed. Since I was not experiencing cramping and the baby had a heartbeat, we did not get overly concerned. Two days following my ultrasound, I lost the baby. Since the pregnancy that resulted in a miscarriage, it has been a long, stressful journey for us.

I decided to seek medical treatment for our infertility. I received an official diagnosis and began infertility medications. I again became pregnant from oral infertility medications and a shot to induce ovulation, only to lose the baby again the week after getting a positive pregnancy test. I was devastated. It took so long to even conceive and then to not be able to maintain a pregnancy only added to the frustration and heartbreak.

I sought out a second opinion following the two miscarriages that happened in a row to determine if there were other factors contributing to why I couldn't maintain a pregnancy. After switching clinics we continued to use medications to help with the infertility. One of these was a subcutaneous shot that induces ovulation and is based on results of an ultrasound. This shot is given at a very specific time and is usually given the night of the ultrasound unless the ultrasound results indicate otherwise. This system worked fine for awhile. I was able to have some of my ultrasounds in Rugby and some of them I traveled down to Bismarck. I would get my results and then if needed, go pick up my shot at my local pharmacy in Rugby. Then in the spring of 2016 I received a letter from my insurance company stating that a medication I was receiving was considered to be a specialty medication and I would no longer be able to get it at my pharmacy. There were several options listed in North Dakota, none of which was my pharmacy that I fill at, and mostly mail order or out of state pharmacies. After this change, I ended up having to pay cash at my local pharmacy due to immediate need of the medication. The next time I was able to pick it up at a pharmacy in Bismarck that I randomly picked off of BCBS's list. This was a huge inconvenience for me since not all of my ultrasounds were done in Bismarck. I also didn't want to spend the money on the medication and order ahead of time from a mail order pharmacy, only to get ultrasounds results indicating that I didn't need the medication, especially when insurance money spent on infertility services has a lifetime maximum that doesn't take much to meet. So this was my first

experience with so called "specialty" pharmacy. Hugely inconvenient to me and at a higher expense to me due to my pharmacy not being able to bill for a medication that I needed.

My next experience once again came at an additional wasted cost to me. My husband and I ended up going through IVF this past November and again in January. Even though I did not want to resort to mail order pharmacy for all of my medications, I was left without much choice. The first round of IVF, I ordered all of my medications through Prime Therapeutics Specialty Pharmacy, the pharmacy associated with my BCBS plan. I received all of my medication in a timely and appropriate manner. I actually thought to myself, ok that wasn't all that bad. Well, what I didn't realize is that the whole course of medication can change and is all based on my personal response which is measured with labs and ultrasounds. However, since I didn't have the option to pick up my meds locally following my lab and ultrasound, I had to make sure I had enough medication on hand and have it ordered ahead of time. This resulted in me having multiple excess medications on hand and essentially wasting money of insurance benefit I had toward infertility services that could have been used for other services. I still have approximately $1000.00 worth of medications from the IVF cycle sitting at my house that I ended up not needed. Since I used up all of my lifetime maximum of $20,000 infertility benefit, that additional $1000 would have been really nice to go toward the procedure instead of wasted medication.

My 3rd experience was even worse and could have been very detrimental. Since our first cycle of IVF did not work, we decided to proceed with a frozen embryo transfer. I did not need a lot of medications for this cycle which was a relief. Once again, the one that I did need required some lab and ultrasound monitoring with dose adjustments made based on the results. I called to order from Prime Therapeutics Specialty Pharmacy at the end of December. They proceeded to tell me that they were out of stock and they would put an override in place for me to get it at my local pharmacy. This worked out great! As our cycle proceeded, it seemed like I was going to need more medication. I did the math and I would have enough to get me through until the exact day of my ultrasound. My medication outline indicated that I would need two doses beyond my ultrasound date. As much as I did not want to order a medication just for two additional doses, I was left with no choice because I couldn't risk the chance of ruining the cycle. This medication had an out of pocket cost to me of $630 and I didn't even know if I would need it for sure. Once again, if I would have been able to pick this up at my normal pharmacy, I could have waited until I was completely out of medication to go in and pick up more so that none would go to waste. I called Prime Therapeutics Specialty on Monday January 9th. I had been told in the past that as long as I called before 5PM EST that I would received the medication next day. Well the patient care specialist that I talked to that day indicated that it wouldn't ship out until Tuesday and would arrive on Wednesday. I figured this would still work out since I wouldn't need a dose until Thursday morning. I received an automated phone call Wednesday morning stating that I had a package that was going to be delivered that day. When I got home from work that evening, there was no package at my door. I waited all evening, knowing that sometimes the UPS driver delivers late. I finally called into Prime Therapeutics at 9:45. They proceeded to tell me that the driver technically had until 11 PM to make the delivery. I went to bed, knowing that my dog would wake me if he did deliver that evening. The next morning, there was still no package. I called Prime Therapeutics right away Thursday morning to get a tracking number and information on where the package was. I was very concerned

because the temps that week had highs in the negative degrees and this was a liquid injectable medication. After over 30 minutes on the phone I was given a tracking number and told that the package was delayed one day and would be arriving later Thursday afternoon. The package was delivered at 7:08 PM on Thursday January 12th, 2017 and was completely frozen. It was not packaged in any special type of packaging, simply a cardboard box. It also had the wrong directions on it due to them filling the prescription from my first IVF cycle instead of the new prescription from my second cycle which are two completely different processes and doses. I called Prime Therapeutics once again to receive directions on how to proceed. They were not able to give me an answer but told me that they would have a pharmacist call me back to talk to me about it. I had a pharmacist finally call me back an hour later. I was instructed that the medication was no longer stable to be used. I was instructed to call Prime Therapeutics back yet again the next morning because there was nothing more he could do for me to get the medication or for me to get refunded for the damaged medication. He told me that he made notes in my account as to what had happened and they would be able to help me the next morning during normal business hours. I went to bed, hoping that I enough left in my current vial to squeeze out for my morning dose.

I called Prime Therapeutics again the following day for instruction on how to proceed with returning the medication, getting and refund, and getting the medication locally as I would need it immediately. Luckily I had been proactive with my local pharmacy and asked them to make sure they had it on hand for me in case the delivery had been delayed again. They had been given an override to bill before so I was hoping that they could again. I spent 46 minutes with them on the phone, over what should have been my lunch break. When I called, there was nothing in my account indicating what had happened. I got asked multiple times if I spoken to the pharmacist and if I could use the medication. After explaining the situation multiple times and getting transferred to multiple people it seemed everything was worked out for UPS to pick the medication up at my house, get a refund, and go pick up my medication at my local pharmacy. By the time my local pharmacy closed at 5:30 PM Friday January 13th, 2017 there still wasn't an override in place for them to be able to bill it even though I had called back yet again at 4:30 PM and spent another 15 minutes on the phone. I decided to wait it out since my last dose of this medication was Saturday morning and if I was not able to get the final dose out of my current vial I would go and get it regardless of whether it could be billed to Blue Cross Blue Shield. Somehow, I got very lucky and there was enough overfill in the vial of medication I had on hand that allowed me to get 3 extra doses out of it to complete my course of medication.

In regards to the return of the medication and the refund, that situation still has not been resolved as I write this. I was instructed that the package had been flagged for pickup and I was to leave the package outside starting Monday January 16th and UPS would attempt 3 consecutive pickups. The package was still there Monday evening and Tuesday morning. I figured UPS was just busy but then when I got home from work Tuesday evening I had a package that had been delivered from UPS sitting right next to it. This was after Prime Therapeutic's normal business hours so I called the next morning as we were driving to our appointments to let them know that the package had not been picked up and no refund had been issued. After getting transferred multiple times again, I spoke to someone who told me that could see in the notes that it was supposed to be flagged for pickup but it wasn't actually ever flagged.

The lady told me that she had it flagged and when we returned Thursday evening from our appointments the package was finally gone. It has been one week since the package was picked up and I still haven't received a refund of my $630. So I will have to call back again to inquire about this.

This could have been very detrimental to me. I was very lucky that there was enough extra medication in my vial and also that I had been proactive with my local pharmacy to make sure they had it on hand in case I needed it. If I would have missed doses of this medication, it could have potentially screwed up our whole cycle of in vitro fertilization which we had already paid thousands of dollars for out of our own pockets since I do not have any insurance benefit left for these services.

Going through infertility and IVF is a very stressful situation the way it is. This situation added to the stress immensely. They claim your chances of success are better the less stress you have and I hope that this didn't have a detrimental effect to our cycle. I hope my story conveys to you the amount of extra stress this situation put me under during this critical time in my life. I have spent over 2 hours of my time on the phone with Prime Therapeutics over this situation, and it still isn't resolved. We were able to move forward with the frozen IVF cycle and are still waiting to find out the results. I know for a fact, none of this would have happened with my local pharmacy which provides excellent and timely care. When Prime Therapeutics claims they have a pharmacist on call 24/7 it is one that calls you back at their convenience. My local pharmacy is also accessible 24/7 if need be and they help you in a timely manner and provide face to face care and service. When going through a situation like infertility and IVF having compassionate care is important and there is no way any mail order pharmacy or so called "specialty" pharmacy will provide more compassionate care than my local pharmacy.

SB2301 2/7/17 #1

February 7, 2017

PROPOSED AMENDMENTS TO SENATE BILL NO. 2301

Page 2, after line 11, insert:

SECTION 2. APPLICATION. This Act applies to contracts and agreements in effect on and after the effective date of this Act.

Renumber accordingly

1

Testimony of Howard C. Anderson Jr. on Senate Bill No. 2301

March 20, 2017 before the House Industry Business and Labor (IBL) Committee. Peace Garden Room at 8:30 AM. Representative George Keiser Chairman.

Chairman Keiser and members of the House IBL Committee.

It is my intent with this bill to address some problems we see occurring in the pharmacy industry. I am a pharmacist myself with a long history in community and hospital pharmacy in North Dakota.

"Specialty drug" is a term being used in the pharmacy industry to identify drugs purportedly needing special handling, strict requirements before prescribing, or in filling and refilling prescriptions.

There has been a fairly recent tendency for the Insurance and Pharmacy Benefit Manager industry to attempt to add drugs to the Specialty drug list, which appears to make them eligible to be dispensed only by a specialty pharmacy, often owned by that same insurance company or pharmacy benefits manager.

This bill attempts to keep that practice to a minimum and make sure that our community and hospital pharmacies can continue to serve their patients as their needs change and their therapy becomes more complex.

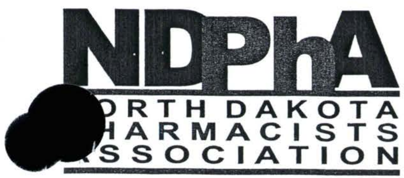
We continue to hear reports of insurance companies requiring accreditation, often targeted to approve only their own facilities, before a pharmacy is allowed to provide service to patients needing these "specialty drugs".

Mike Schwab and the pharmacists are here and they will give you information on specific instances and more information on how this bill will help them serve their patients.

Thank you,

Howard

2



SB 2301

House Industry, Business and Labor Committee

March 20, 2017 – 8:30 am

Rep. George Keiser – Chairman

Chairman Keiser and members of the committee, for the record, my name is Mike Schwab, the Executive Vice President of the North Dakota Pharmacists Association (NDPhA). We are here today in support of SB 2301.

I will do my best to go through the bill in detail section by section. First, I would like to start off by turning your attention to Page 1 – Line 11 – Letter C. Here you will see a definition of "specialty drug". Some of you might ask, what is a specialty drug? I wish I had an easy answer for all of you. The reality, there is no standard definition of what constitutes a specialty drug. However, the "specialty drug market" is the fastest growing area of the pharmaceutical market. Pharmacy Benefit Managers (PBMs) and insurers have created and maintain specialty drug lists. The problem is that PBMs and insurers all have different lists and in recent years these lists have grown at an extremely fast past. All the large PBMs here today (Express Scripts, Prime Therapeutics and CVS/Caremark) all own and control their own Specialty Mail Order Pharmacies. The specialty lists are growing at a rapid pace like never seen before in pharmacy and along with the expansion of so-called "specialty" drug lists prices have followed suit. The two largest pharmacies in this country by volume are now CVS/Caremark and Express Scripts. The three largest PBMs control roughly 80% of the covered lives. In very short period of time, Express Scripts, CVS/Caremark and Prime now control over 50% of the specialty drugs dispensed in this country according to Drug Channels and that percentage continues to grow.

Right now, PBMs define and decide which drugs they want to include on these specialty list, when they want to add drugs and how long they will stay on the list. Don't get me wrong, some drugs that are typically administered in a hospital or clinic setting should be considered a specialty drug. Retail community pharmacies, hospital community pharmacies and long-term care pharmacies have been dispensing a lot of these drugs for many years and in some cases decades.

The PBMs will lead employers and others to believe that only they can provide specialty drugs or that a pharmacy needs to be accredited or dual accredited to provide services. They will lead you to believe that they provide "unique" specialty pharmacy protocols to maximize safety and adherence. I would like to talk to you about those "unique clinical protocols". If you look at their websites or review some of the materials they present to employer groups you will see some the following "unique clinical protocols": (1) counsel the patient, (2) provide refill reminders, (3) communicate with your physician, (4) address cost barriers, (5) provide pill splitting, (6) provide utilization reports, and (7) provide educational materials. Chairman and members of the committee, pharmacists have been providing these services daily for many years. There is nothing "unique" about those protocols and those are things pharmacists do every day.

The PBMs may lead you to believe that they can maximize safety by providing the specialty medication through their own mail order pharmacy. I am dumbfounded because the PBM wants you to think that a nurse or pharmacist on the phone who doesn't know the patient, has no patient relationship and is calling from who knows where will do a better job of counseling the patient and showing the patient how to self-administer an injectable drug over the phone or by sending them information to read in the mail. I don't know about you but personally, I would rather have the choice of having my trusted pharmacist show me how to provide the self-injection (which pharmacists are trained to provide!) and be available to counsel me with a face-to-face visit. After all, the local pharmacist year after year is one of the most trusted and most accessible healthcare providers in our healthcare system and this bill aims to keep it that way.

In addition, these drugs that are supposedly so "special" they will just show up in your mail box or be sitting on your front steps (must not be too special if the PBM just throws it in the mail) waiting for you to pick up the phone to talk to someone you hopefully can understand and hopefully already knows your medical health history. There is growing evidence regarding the amount of waste associated with mail order pharmacies. Patients finding their specialty drug frozen on their door step in the winter or baking in their mail box during the summer only adds to "waste" in the system and higher costs for the employer the bill. We have multiple

examples of patients calling their local pharmacist to ask them if they should still take the medication because it was frozen. Thankfully they called their local pharmacist!

Another patient frustration which reduces their quality of life and potential impacts their immediate health is that fact that sometimes the specialty medication does not show up in the mail when it is supposed to or never shows up at all. Of course, when this happens, the local pharmacy provider is now good enough to serve the patient and comes to the rescue. The PBM will provide an override code and allow the local pharmacist to provide an emergency fill or short-day supple of the medication for the patient but only this one time. In some cases, the PBM will allow the pharmacy to provide the first and second fill of the specialty drug but after that due to the benefit design, the patient must then get the drugs from the PBMs mail order pharmacy. The pharmacist does all the work and provides the service and then the PBM mandates through the benefit design the drugs must come from their mail order pharmacy. Many of these products are injectable, which is important, because, historically, injectable products have been delivered mostly through the community pharmacy channel. If you look at the FDA pipeline section, the majority of the specialty drugs are in fact injectable drugs, which have traditionally been easier for community pharmacies to deliver and provide high quality services. When looking at a competitive analysis, PBMs have developed mechanisms for the delivery of specialty drugs that allow the benefit sponsor to push selected specialty drugs away from the community pharmacy to a select number of specialty pharmacy providers which they often own. This PBM – Specialty pharmacy relationship makes it difficult for individual benefit sponsors to have real choice when selecting a distribution methodology for specialty drugs.

Page 1 – Line 18 – Number 2. You will probably hear each PBM oppose this provision. We understand and can respect their position. This still does not change the reason and rationale for our support of this section.

Chairman and members of the Committee, the public, employers, policymakers and providers have been asking for more pricing transparency in the prescription drug market and more specifically the PBM industry for years. This provision requires the PBM to disclose to a plan sponsor contracted payer (the employer who is ultimately paying the bill), if there is a difference in what the pharmacy was paid for a drug and what the PBM actually charged the

employer. This is called "spread pricing" in the PBM industry (pay the pharmacy low and bill the employer high) and this is where PBMs generate a large portion of their revenue. While not Illegal, but highly suspect and secret, pharmacies are tired of shouldering the "myth" that community pharmacies often cost more than PBM owned pharmacies. A large number of employers have no idea spreading pricing even takes place. The PBM gets to create the invoices sent to the employer. The employer is not directly billed by the pharmacy nor does the employer have any idea what the pharmacy was actually paid. This provision would show the employer what the PBM charged them as well as what the community pharmacy was paid. We once heard a PBM lobbyist tell us, if you want us to show the "spread" then we want the pharmacies to show their reimbursement as well. Well, that time has come as we have been backed into a corner and we don't have anything to hide. Not only does this provision provide employers with important information and transparency when they are trying to make an informed contracting decision, but it allows the employer to evaluate if they are getting a fair deal for the services they are buying.

The next set of provisions, Page 1 – Line 22 – Number 3. This provision states the PBM would have to adhere to fair competition and no-self dealing with their administrative functions and the pharmacies that they own and would require a firewall between the administrative functions and pharmacy operations of the PBM. Due to their administrative functions as a PBM, they receive all the patient drug information directly from all their competing pharmacies and they need to keep that administrative information separate from their pharmacy business operations. This section might be seen as "given" in a contractual relationship, but we support the clarity of this section.

On Page 2 – Line 4 – Number 4. Some PBMs have taken it upon themselves to now require pharmacies jump through a bunch of hoops and become "accredited" to be in the PBMs specialty pharmacy network and to be allowed to dispense specialty drugs to patients. The accreditation requirement is only one aspect of some PBMs attempt to carve pharmacies out of the "specialty" market or other pharmacy networks for that matter. On top of accreditation, some PBMs also require pharmacies adhere to a slew of reporting requirements as well as certain assurance measures. Reporting requirement and assurance measures are one thing.

However, a number of the reporting and assurance measures have egregious "fines" attached to them. If you look at the criteria for accreditation, a large portion of the requirements are already in place at a pharmacy due to state and federal mandates such as FWA policies, disaster plans, mandated patient consultation, maintain patient profiles, follow-up for complex patients, HIPPA, etc. Pharmacies are already highly regulated (unlike PBMs) by State and Federal laws and rules and authorized to dispense any and all drugs their licenses and certifications allow.

I would like to thank you for your time and attention today. I would be happy to try and answer any questions. I know there are a number of other individuals who would also like to share testimony with all of you today.

Respectfully Submitted,

Mike

Mike Schwab

NDPhA - EVP

Mar 20, 2017 SB 2301 3

Members of the House Industry, Business and Labor Committee, thank you for the opportunity to submit testimony on pending legislation S.B. 2258 and S.B. 2301 and the need increase enforcement and regulation with respect to Pharmacy Benefit Managers (PBMs). This testimony documents the compelling need for this legislation to protect consumers and health care providers, and regulate PBMs in North Dakota. As explained in this testimony, the proposed legislation includes policies that are needed to protect consumers and providers from inconsistent and unfair practices by PBMs and provide a more competitive marketplace.

The comments in this testimony are based on 30-plus years of experience as a private sector antitrust attorney and an antitrust enforcer for both the Department of Justice and the Federal Trade Commission ("FTC"). From 1995 to 2001, I served as the Policy Director for the FTC's Bureau of Competition and the attorney advisor to Chairman Robert Pitofsky. At the FTC, I helped direct the first antitrust cases against PBMs. Currently, I work as a public interest antitrust attorney. I have represented consumer groups, health plans, unions, employers, and even PBMs on PBM regulatory and competitive issues. I have testified before Congress, numerous state legislatures and three times before the Department of Labor on PBM regulation, and was an expert witness for the State of Maine on its PBM legislation.[1]

The following testimony explains why the proposed legislation is necessary to protect consumers, health care providers and competition.

I. Background

PBMs increasingly engage in anticompetitive, deceptive or egregious conduct that harms consumers, health plans, and pharmacies alike. In a nutshell, both consumers and pharmacies suffer as consumers are increasingly denied a choice in their level of pharmacy service by PBMs. PBMs exercise their power to restrict consumers to the PBM's own captive mail order and specialty pharmacy operations, reducing choice and quality for many. Consumers and their health plans also suffer when health plans are denied the benefits of the PBMs' services as an honest broker, which drives up drug costs, and ultimately leaves consumers footing the bill for higher premiums.[2]

Why do consumers care about restricted access to pharmacies? Because community pharmacists are the most accessible health care professionals; and in many markets, such as rural markets which are prominent in North Dakota, they may be the only accessible professional. Because community pharmacies provide consumers with valuable clinical services and counseling, often free of charge. Because some pharmacies offer drugs at lower prices than the PBMs. Egregious PBM conduct jeopardizes these types of programs that consumers highly value. As community pharmacies are already economically efficient and operate on very minimal margins, reduced consumer access to these pharmacies would, in the end, likely result

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[1] The views expressed herein are my own and do not necessarily represent the views of any individual clients.
[2] Often health plans and large employers are silent on complaining about the PBMs out of fear of retaliation since they must do business with PBMs. In response to criticism during the Express Scripts/Medco merger that employers did not publicly express concern over the merger, Senator Herb Kohl stated that "it is notable that no large employer who privately expressed concerns to us wished to testify at today's hearing, often telling us that they feared retaliation from the large PBMs with whom they must do business." Statement of U.S. Senator Herb Kohl on the Express Scripts/Medco merger (12.6.2011).

in harm to other consumers who rely on these community pharmacies.

Similarly, consumers also care about rising health care costs, including out-of-pocket costs for prescription drugs. PBMs have a profound impact upon drug costs. If PBMs are unregulated they can continue to engage in conduct that is deceptive, anticompetitive, and egregious. For this system to work effectively, PBMs must be free of conflicts of interest that arise from owning their own pharmacies. What health plans and employers are fundamentally purchasing is the services of an "honest broker" to secure the lowest prices and best services from both pharmaceutical manufacturers and from pharmacies. When the PBM is owned by the entity it is supposed to bargain with or has its own mail order operations there is an inherent conflict of interest, which can lead to fraud, deception, anticompetitive conduct, and higher prices. The three major PBMs – Express Scripts, CVS/caremark and Optum Rx -- clearly face that conflict since they own mail order operations, specialty pharmacies, and in the case of CVS Caremark – the second largest retail pharmacy chain and the dominant long-term care pharmacy in the U.S.

In recent years, the major PBMs—including those with a clear conflict of interest in their cross-ownership with pharmacies—have engaged in a variety of anticompetitive and anti-consumer practices.

II. Chronic Anticompetitive and Consumer Protection Problems in the PBM Market

PBMs are like other healthcare intermediaries that manage transactions by forming networks and transferring information and money. As a former antitrust enforcer, I can tell you that there are three essential elements for a functioning competitive market: (1) transparency, (2) choice and (3) a lack of conflicts of interest. This is especially true when dealing with health care intermediaries such as PBMs and health insurers where information may be difficult to access, arrangements are complex and clouded in obscurity, and there may be principal-agency problems. On all three of these elements the PBM market receives a failing grade.

Why are choice, transparency, and a lack of conflicts of interest important? It should be obvious. Consumers need meaningful alternatives to force competitors to vie for their loyalty by offering fair prices and better services. Transparency is necessary for consumers to evaluate products carefully, to make informed choices, and to secure the full range of services they desire. In both of these respects the PBM market is fragile at best. There is certainly a lack of choice especially for those plans that are dependent on the top tier big three PBMs (Express Scripts, CVS Caremark and Optum) which have an approximate 80% share of the market. And PBM operations are very obscure and a lack of transparency makes it difficult for plans, including government buyers, to make sure they are getting the benefits they deserve.

When dealing with intermediaries, it is particularly critical that there are no conflicts of interest. A PBM is fundamentally acting as a fiduciary to the plan it serves. The service a PBM provides is that of being an "honest broker" bargaining to secure the lowest price for drugs and drug dispensing services. When a PBM has an ownership interest in a drug company or has its own mail order or specialty pharmacy dispensing operations, it is effectively serving two masters

and may no longer be an "honest broker."

Moreover, when a PBM has its own pharmacy operations there are a myriad of competitive problems. Who will effectively monitor and audit the company-owned pharmacies? A pharmacy chain can use its PBM affiliate to disadvantage rival pharmacies, reducing reimbursement, and excluding pharmacies from networks. What about competitively sensitive information such as prices and costs? Where a pharmacy knows its rivals costs and pricing, it does not have to compete as hard. Ultimately consumers lose through less choice and higher prices.

The rapidly increasing drug costs which effectively lead to higher drug rebates for the PBMs leads one to question which master the PBM is serving. It increasingly appears that PBMs profit from higher drug prices, because they lead to higher rebates.

Competition and choice are crucial for a market to work effectively. North Dakotans should have the choice in how they value pharmacy services. Some choose community pharmacies, others who value one-stop shopping choose their local supermarkets, and others choose chains. This choice is important because competitors have to respond to this choice by improving services and lowering prices.

The legislation presented to this Committee is vital to provide needed protections to consumers, community pharmacies and payors.

Who Speaks for the Consumer – The Community Pharmacist

One important aspect of pharmacy services is the service pharmacists provide in assisting consumers in dealing with insurance companies and PBMs. Too often consumers are lost in a system where the PBM says "we don't have any choice, it's the employer who refuses coverage" and the employer says "we just do what the PBM tells us to do." No one takes responsibility or provides an answer. Who is there to protect the consumer?

The pharmacist is the advocate for the consumer. When PBMs create barriers patients typically seek help from their pharmacist to navigate their pharmacy benefit. Consumers can not battle with the PBM or insurance company. For these consumers, pharmacists act as an advocate, guiding consumers to use the lowest price drugs, explaining co-pays, and determining access. When a particular policy is problematic, the pharmacist will often work through it with the patient, providing explanation and even advocating on behalf of the patient with the PBM—going far beyond the tasks for which the pharmacist is paid.

Moreover, not only are pharmacies not paid for such services, but pharmacies are assessed ancillary fees by the PBMs not provided them at the point-of-sale to consumers. Additionally, in some instances in which the cost of a consumer's co-pay for a drug exceeds the cost of the drug itself, PBMs will claw-back the additional amount from the pharmacy. These practices place pharmacies in a position of not knowing what true reimbursement will be until months after they have dispensed the medications.[3] Such practices put pharmacies in peril of

[3] These practices also increase costs to the federal government. The Centers for Medicare and Medicaid Services

being able to continue servicing consumers.

S.B. 2258 provides protection for pharmacies from charges that are not apparent at the point-of-sale or at the time the claim for the dispensed drug is processed by the PBM. It also prevents a PBM from charging a patient a co-pay that exceeds the cost of the medication and prohibits the PBM from automatically clawing-back from the pharmacy the portion of the co-pay that has been patient by the patient. These provisions are necessary to allow pharmacists to continue advocating for patient coverage and protecting patients from egregious PBM practices.

III. A Broken Market Leads to Escalating Drug Costs and Rapidly Increasing PBM Profits

What is the result of this dysfunctional market? PBMs entered the health care market as "honest brokers" or intermediaries between health care entities. However, the role of the PBM has evolved over time and increasingly PBMs are able to — "play the spread" – by not fully sharing the savings they purportedly secure from drug manufacturers. As a result PBM profits have skyrocketed over the past dozen years. Since 2003, the two largest PBMs—Express Scripts/Medco and CVS Caremark— have seen their profits increase by almost 600% from $900 million to almost $6 billion.

If the market was competitive, one would expect profits and margins would be driven down. But as concentration has increased, the exact opposite has occurred.

There is tremendous concern over rapidly increasing drug prices which threaten our nation's ability to control the cost of health care. While PBMs suggest that they are there to control costs, these claims must be carefully scrutinized. The concern of a PBM is to maximize profits and that means maximizing the amount of rebates they receive. Since rebates are not disclosed, this is an incredibly attractive source of revenue. PBMs can actually profit from higher drug prices, since this will lead to higher rebates.

Would PBMs withhold their negotiating punch to secure higher rebates? We do not have to guess that this is occurring. PBMs have used similar strategies in the past. Indeed, as noted below state enforcers have attacked sweetheart deals PBMs arranged with drug manufacturers to force consumers to use higher cost, less efficacious drugs, in order to maximize rebates and secure kickbacks. They held back their negotiating muscle to allow prices to escalate to maximize rebates.

Facing weak transparency standards, the largest PBMs frequently engage in a wide range of deceptive and anticompetitive conduct that ultimately harms and denies benefits to consumers. Some PBMs secure rebates and kickbacks from drug manufacturers in exchange for exclusivity

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(CMS) recently issued a report concerning the ancillary fees known as direct and indirect remuneration. CMS reported that compensation and rebates PBMs receive from transactions beyond the pharmacy point-of-sale is double the rate of gross drug spending by CMS on Medicare Part D prescriptions. Such ancillary charges to pharmacies place more burden on Medicare beneficiary cost-sharing and increasing Medicare's costs for these beneficiaries. CMS, Medicare Part D – Direct and Indirect Remuneration (January 19, 2017), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html.

arrangements that may keep lower-priced drugs off the market. PBMs may switch patients from their prescribed drug to a more expensive drug to take advantage of rebates that the PBM receives from drug manufacturers. PBMs often do not pass through rebates secured from drug manufacturers to payors, and instead are accounted for as a reduction in cost of revenues, allowing the PBMs to hide profits. In fact, Medco was the last PBM to publicly disclose rebates in 2012. In short, PBMs derive enormous profits at the expense of the health care system from the ability to "play the spread" between pharmaceutical manufacturers, pharmacies and health care plans.

No other segment of the health care market has such an egregious record of consumer protection violations as the PBM market. Between 2004 and 2008, Express Scripts and CVS were the subject of six major federal or multidistrict cases over allegations of fraud; misrepresentation to plan sponsors, patients, and providers; unjust enrichment through secret kickback schemes; and failure to meet ethical and safety standards. One of the most common forms of egregious conduct identified was PBMs switching consumers to higher cost drugs, that often were less efficacious, in order to maximize rebates. These cases appended to this testimony, resulted in over $371.9 million in damages to states, plans, and patients so far.

Unfortunately the provisions in the orders in each of these cases have expired, increasing the need for greater regulation and enforcement to ensure that the market functions with transparency, consumer choice, and free of conflicts of interest.[4] These problems are only getting worse. Case in point is the number of recent cases which are either ongoing or have recently settled. In 2014, CVS alone was responsible for over $30 million in penalties concerning violations of the False Claims Act and SEC violations.[5] In 2015, Express Scripts and CVS paid settlement fines to the federal government and to numerous states of over $129 million for illegal prescription dispensing and various violations of the false claims and anti-kickback laws.[6] Currently pending before the Delaware federal district court is a False Claims Act violation brought against Medco (now Express Scripts) on behalf of the U.S., California, Florida and New Jersey over claims the company defrauded state and federal health insurance programs by accepting undisclosed discounts from drug manufacturers and not passing on the savings to its clients, according to a recently amended complaint.[7]

Moreover, substantial private litigation is pending against major PBMs. For example, Optum Rx, has several separate suits filed against it. One by retail chain Kmart which alleged failure to pay reimbursements for dispensed drugs equating to $38 million in damages;[8] another by 55 independent pharmacies alleging illegal conduct serving to inflate patient costs while

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[4] For a more detailed analysis of the federal and state cases against the PBMs, *see* David A. Balto, *Federal and State Litigation Regarding Pharmacy Benefit Managers*. http://www.dcantitrustlaw.com/assets/content/documents/PBM/PBM%20Litigation%20Updated%20Outline%20-%201-2011.pdf.

[5] *See* Testimony of David A. Balto, "The State of Comeptition in the Pharmacy Benefits Manager and Pharmacy Marketplaces," before the House Judiciary subcom. On Regulatory Reform, Commercial and Antitrust Law, Appx. A (Nov. 17, 2015), http://dcantitrustlaw.com/assets/content/documents/testimony/PBM%20Testimony. Balto_November%2017%202015.Final.pdf.

[6] Id.

[7] *John Doe v. Medco Health Solutions Inc., et al.*, Case No. 1:11-cv-00684 (D. Del.).

[8] *Kmart Co. v. Catamaran Co.*, Case No. 2015-L-008290 (Ill. Ct. Cl. Aug. 31, 2015).

simultaneously underpaying pharmacies;[9] and several others filed in 2016 alleging that Optum is overcharging patients for prescription drugs and pocketing the overcharge.[10] Express Scripts is currently facing a $13 billion lawsuit by its largest client Anthem for overcharges for prescription drugs.[11] Additionally, Express Scripts is facing several antitrust conspiracy suits in which plaintiffs have alleged Express Scripts engaged in a conspiracy with other major PBMs to exclude competing compounding pharmacies from their network, effectively forcing the competition to close and routing patients to the PBMs captive pharmacies. These cases have survived Express Scripts' motions to dismiss and one is set for a jury trial beginning in May 2018.[12]

IV. Legislation is Vital to Inform Payors and Protect Consumers

As a general matter it is essential to provide transparency for consumers, which helps them to adequately evaluate products carefully, to make informed choices, and to secure the full range of services they desire. In these respects the PBM market is fragile at best. PBM operations are very obscure and a lack of transparency makes it difficult for plan sponsors to make sure they are getting the benefits they deserve.

Responding to the numerous enforcement actions, both a handful of states and Congress have taken measures to enact transparency provisions by requiring some degree of disclosure of rebates and other revenue. In the multistate enforcement action against CVS Caremark, 30 state attorneys general required rebate disclosure. Additionally, the Department of Labor ERISA Advisory Council recommended PBMs be required to disclose fees and compensation to sponsors of ERISA health plans.[13] Finally, some large sophisticated health plans have negotiated for greater transparency.[14]

Although settlements from litigation and negotiations have helped to address some issues, without legislation, a lack of transparency allows PBMs to "play the spread" – the difference between a PBM's expenditure and the revenue it takes in – leading to higher costs for plan sponsors and patients. PBMs earn enormous profits by negotiating rebates and discounts with drug manufacturers in exchange for promoting certain drugs on their preferred formulary or engaging in drug substitution programs. PBMs also negotiate contracts with pharmacies to determine how much the pharmacists will be paid for dispensing medication and providing services. By paying a lower reimbursement rate to pharmacies, but failing to adequately disclose reimbursement rates and manufacturer rebates, PBMs can generate more revenue. In both

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[9] *Albert's Pharmacy, Inc. et al v. Catamaran Corporation*, Case No. 3:15-cv-00290 (M.D. Pa. Feb. 9, 2015).
[10] *See, e.g, Stevens v. UnitedHealth Group, Inc. et al.*, Case No. 16-cv-03496 (D. Minn.).
[11] *Anthem v. Express Scripts*, Case No. 16-cv-2048 (S.D.N.Y.)
[12] *HM Compounding Services v. Express Scripts*, Case No. 14-cv-01858 (E.D. Mo.); *Precision RX Compounding, LLC et al. v. Express Scripts*, Case No. 16-cv-00069 (E.D. Mo.).
[13] *See* PBM Compensation and Fee Disclosure, Report by the ERISA Advisory Council, Department of Labor (2014), *available at* http://www.dol.gov/ebsa/publications/2014ACreport1.html.
[14] Linette Lopez, The companies you've never heard of are about to incite another massive drug price outrage, Business Insider (Sept. 12, 2016) (reporting that some of America's biggest employers including American Express, Macy's and Coca-Cola have created an organization called the Health Transformation Alliance with the aim of breaking with "existing marketplace practices that are costly, wasteful, and inefficient, all of which have resulted in employees paying higher premiums, copayments, and deductibles every year" including PBMs), http://www.businessinsider.com/scrutiny-express-scripts-pbms-drug-price-fury-2016-9.

respects, PBMs can "play the spread" by failing to disclose these forms of indirect compensation. The failure to disclose these payments denies purchasers important information that impacts their buying decisions. [15] As a result, this lack of information often results in higher costs for consumers, health plans, employers, and other plan sponsors.

PBMs are free to "play the spread" between manufacturers, pharmacists and plans because of a lack of disclosure. Unclear and inadequate disclosure of rebates and discounts undermine the ability of plan sponsors to compare competing proposals. Because rebates, discounts, and other fee structures remain undisclosed, plan sponsors cannot clearly identify and choose PBMs offering the highest value services. PBMs' promise of controlling pharmaceutical costs has been undercut by a pattern of conflicts of interest, self-dealing, deception, and anticompetitive conduct. The dominant PBMs have been characterized by opaque business practices, limited market competition, and widespread allegations of fraud.

Increased disclosures by PBMs have resulted in price decreases and significant savings for health plans. For example, in the corporate context, a recent report revealed that Meridian Health System discovered that its drug benefit increased by $1.3 million within the first month of contracting with Express Scripts for PBM services.[16] Meridian discovered that they were being billed for generic amoxicillin at $92.53 for every employee prescription; however Express Scripts was paying only $26.91 to the pharmacy to fill these same prescriptions.[17] The result was a spread of $65.62 going back to the PBM. Meridian canceled its contract and switched to a transparent PBM which saved Meridian $2 million in the first year of its contract.

The provision of S.B. 2301 which requires PBMs to provide more transparency for employers and requires the PBM to disclose if the PBM practices spread pricing is vitally important for the employer to make informed contracting decisions to better service its beneficiaries.

V. Protecting Patient Choice and Eliminating Conflicts of Interest

The legislation before this Committee serves to protect patient choice. As consumers and patients we all understand the critical importance of patient choice. Only where consumers have the full range of choices does the competitive market thrive. Unfortunately, because PBMs have their own pharmacy operations – through retail stores, mail order, or specialty pharmacy – they are increasingly engaging in conduct that restricts patient choice and leads to higher costs and worse health care.

Forcing Consumers to use Mail Order

The major PBMs make a large portion of their profits by forcing consumers to use mail order. The major PBMs often restrict network options to drive consumers to their operations.

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[15] Robert Restivo, Testimony before the Department of Labor ERISA Advisory Council at 15 (August 20, 2014) ("the [PBM] industry is beset with a lack of transparency that is difficult to deal with even for the largest employers."), *available at* http://www.dol.gov/ebsa/pdf/ACrestivo082014.pdf.

[16] Katherine Eban, *Painful Prescription*, Fortune Magazine (Oct. 10, 2013).

[17] Id.

Mail-order may be more costly, may result in significant waste, and fails to provide the level of convenience and counseling that many consumers require. Consumers may have existing relationships with a community pharmacy and may not wish to leave the pharmacist they know and trust to be served by a mail order robot. Others simply enjoy the ability to one-stop-shop and prefer the convenience of their supermarket pharmacy. The bottom line is that consumers are left worse-off when they are unable to choose the level of pharmacy care they desire.

Preventing Vulnerable Consumers from Using Their Community Specialty Pharmacy

The ownership of specialty pharmacies exacerbates the conflict of interest problem. Restrictive networks raise significant concerns for the over 57 million Americans that rely on specialty drugs.[18] Specialty drugs are typically expensive treatments that require special handling or administration. These drugs provide treatment for our nation's most vulnerable patient populations who suffer from chronic, complex conditions such as hemophilia, Crohn's Disease, Hepatitis C, HIV/AIDS, and many forms of cancer. The leading PBMs – Express Scripts, CVS Caremark and Optum own their own specialty pharmacies and increasingly force consumers to use their specialty pharmacy. Specialty drugs are expected to be the single greatest cost-driver in pharmaceutical spending over the next decade. The cost of specialty drugs is rising rapidly, with a projected increase to $1.7 trillion in 2030.[19] The leading PBMs' specialty pharmacies account for over 50% of the specialty drug revenue in the United States.[20]

The dominant PBMs are able to force consumers to use their own specialty pharmacies through restrictive networks. These networks can be higher cost and can also disrupt the continuum of care degrading health outcomes and increasing healthcare costs.[21] Patients on specialty drugs often require regular contact and counseling from their pharmacist. For many disease states, the pharmacist and health care team regularly contact the patient to make sure the drug is properly administered, taken on time, and the drug is working effectively. Disrupting this patient-provider relationship in complex and expensive treatment of very sensitive health conditions imposes significant harm to both the consumer and the health plan. We all know there is a profound difference between the personal treatment of an independent pharmacy and dealing with the automated telephone approach of the large PBMs.

Moreover, restrictive networks and steering practices rob consumers of the choice to use their preferred pharmacy and method of distribution; and—with this important rivalry gone—consumers also miss out on the benefits of vigorous competition, including lower prices and

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[18] Laura Hines, *Soaring specialty drug prices leave patients seeking relief*, Houston Chron. (March 15, 2015).
[19] IMS Health, Overview of the Specialty Drug Trend (2014), *available at* https://www.imshealth.com/deployedfiles/imshealth/Global/North%20America/United%20States/Managed%20Markets/5-29-14%20Specialty_Drug_Trend_Whitepaper_Hi-Res.pdf.
[20] Adam Fein, The Top 15 Specialty Pharmacies of 2016, Drug Channels (Feb. 22, 2017), http://www.drugchannels.net/2017/02/the-top-15-specialty-pharmacies-of-2016.html.
[21] The vital service-related role of independent specialty pharmacies was described in my testimony before the United State Senate Judiciary Antitrust subcommittee concerning the Express Scripts-Medco merger. *See* David Balto, Testimony regarding "The Express Scripts/Medco Merger: Cost Savings for Consumers or More Profits for the Middlemen?" before the U.S. Senate Subcommittee for Antitrust, Competition Policy and Consumer Rights, December 6, 2011, *available at* http://dcantitrustlaw.com/assets/content/documents/testimony/SenateJudiciary.ESIMedci.Balto.pdf.

improved service. These restrictive networks deny patients a choice in provider and, given the high-touch nature of services in this area, this choice is highly valued by many consumers. The PBMs' ability to impose restrictive networks harms consumers that depend on the high-cost products and services that are of great, and even life-altering, significance to these vulnerable patients.

Finally, there is the fox guarding the hen house problem. When a PBM has its own specialty pharmacy, it no longer clearly serves the plan – rather, its incentive is to increase profits by forcing consumers into the PBM's specialty pharmacy.[22] The New York Times poses the appropriate question: "pharmacy benefit managers like CVS and Express Scripts…are supposed to help health plans control drug costs. But will they have the zeal to do that if they are making money dispensing these expensive medicines?"[23]

Of critical importance here is the fact that North Dakota community pharmacists are not looking for a "handout" from the PBMs, the state or the federal government; they simply want the ability to compete on a level playing field. This further demonstrates the anticompetitive practices utilized by the PBMs. If a small business community pharmacy is willing to accept the same contract terms as, for example, CVS, but is denied the opportunity to contract, one of two things is happening: either CVS's contract is raising costs for consumers by not offering the lowest price true competition would yield, or consumers are needlessly suffering poorer pharmacy access and choice.

The provisions of S.B. 2258 and S.B. 2301 serve to help eliminate many of the conflicts of interest explained above. The legislation allows a pharmacy to mail or delivery medications as an ancillary service of the pharmacy. This is a practice that North Dakota pharmacists have been providing for over 125 years. Additionally, the legislation provides increase in patient access and choice for patients purchasing specialty medications. By preventing the PBMs to require standards more stringent than federal and state requirement for licensure in the state of North Dakota, and allowing a licensed pharmacy to dispense any and all drugs under that license, the legislation will help ensure adequate pharmacy access and choice for North Dakota consumers.

VI. Conclusion

S.B. 2258 and S.B. 2301 will have a significant, positive impact on North Dakota consumers, providers and employers. PBMs operate with little transparency and inherent conflicts of interest engaging in deceptive practices. Without transparency, PBM profits will continue to rise exponentially at the expense of small business pharmacies and patients. Broadening transparency requirements on PBMs will allow pharmacies to better ably serve their patients by being able to receive fair reimbursement, and allow payors and employers to make informed contract decisions before it enters a deal with the PBM. Conflicts of interest in owning

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[22] Katie Thomas, Specialty Pharmacies Say Benefit Managers Are Squeezing Them Out, New York Times (Jan. 9, 2017), *available at* https://www.nytimes.com/2017/01/09/business/specialty-pharmacies-say-benefit-managers-are-squeezing-them-out.html.

[23] Andrew Pollack and Katie Thomas, Specialty Pharmacies Proliferate, Along With Questions, New York Times (July 15, 2015), *available at* http://www.nytimes.com/2015/07/16/business/specialty-pharmacies-proliferate-along-with-questions.html?_r=0.

mail and specialty pharmacies significantly inhibit patient choice and access to their preferred providers. Allowing increased choice and access to community pharmacy will foster greater competition to the benefit of plans and ultimately to consumers. We urge you to vote to pass both S.B. 2258 and S.B. 2301.

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WRITTEN TESTIMONY OF DAVID A. BALTO TO MEMBERS OF THE NORTH DAKOTA HOUSE INDUSTRY, BUSINESS AND LABOR COMMITTEE REGARDING S.B. 2258 AND S.B. 2301

March 20, 2017

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Appendix A: Cases against Pharmacy Benefit Managers

Appendix A offers a summary of cases against pharmacy benefit managers ("PBMs"). This is not a complete list of all litigation against PBMs. The case summary focuses on cases claiming PBM deception, fraud, or antitrust violations.

Year	Case	Summary
2016	*In Re UnitedHealth Group PBM Litigation*, Case No. 16-cv-3352 (D.MN.)	Class action lawsuit against Optum Rx parent, UnitedHealth alleging Optum required network pharmacies to charge patients unauthorized and excessive amounts for prescription drugs. Optum then clawed back these excessive payments by forcing the pharmacies to pay the unauthorized or excessive charges to Optum after collecting them from the patients.
2016	*Prime Aid Pharmacy Corp., v. Express Scripts, Inc.*, Case No: 2:16-cv-02182 (E.D. Mo.)	Prime Aid Pharmacy files antitrust law suit against Express Scripts for fraudulent scheme and anticompetitive behavior between specialty pharmacies and the specialty pharmacies that Express Scripts owns and operates.
2016	*Express Scripts receives subpoena from U.S. Attorney's Office for the District of Massachusetts*	U.S. Attorney Office seeking information about Express Scripts relationship with drug makers, charitable foundations they own that and provide assistance to federal health care program beneficiaries and specialty pharmacies.
2016	*Express Scripts receives subpoena from the U.S. Attorney of New York*	U.S. Attorney's office seeking information about the firm's relationship with drug makers and prescription drug plan clients and payments schemes to and from both.
2016	*Richard Medoff v. CVS Caremark Corporation, et al.*, Case No: 1:09-cv-00554-JNL-PAS	A securities class action suit against CVS Caremark for False and Misleading Statements related to its merger and profitability related to substantial loss of business after CVS's 2007 merger with Caremark resulted in a 2016 settlement in the sum of **$48,000,000 million** to the class action plaintiffs.
2016	*Anthem v. Express Script, Inc.*, Case No. 16-cv-2048 (S.D.N.Y.)	Anthem has accused Express Scripts of breaching their management services agreement by charging inflated prices and refusing to renegotiate in good faith. Among the several additional claims, Anthem said Express Scripts did not properly comply with regulations set out by the Centers for Medicare & Medicaid Services regarding Medicare Part D claims. Anthem is seeking **$13 Billion in damages.**

2016	*Burnett v. Express Scripts, Inc.*, Case No. 1:16-cv-04948 (S.D.N.Y.)	Express Scripts Inc. and Anthem are accused in a proposed class action of breaching their ERISA fiduciary duties that caused the plan participants to overpay for drug benefits. Specifically, plaintiffs accuse Express Scripts charged "above competitive pricing levels" and Anthem allowed these prices as part of a 10-year contract deal with the pharmacy benefit manager. This case was brought by plans sponsored by Verizon Communications Inc., AmTrust Financial Services and LG&E and KU Energy LLC and their 26,000 combined participants.
2016	*Trone Health Services Inc et al. v. Express Scripts*, Case No.4:16-cv-01250-RLW (E.D. Mo.)	Trone Health Services Inc on behalf of all similarly situated pharmacies in the United State alleging Unfair Competition, breach of contract, breach of implied covenant of good faith and fair dealing, interference with economic advantage, violation of uniform trade secrets act and fraud for the practice of "slamming" to personally enrich Express Scripts. Slamming is the process of utilizing pharmacy information related to customers and customers' prescriptions to forcibly switch customers from Plaintiffs' retail pharmacies to Defendant's own mail-based pharmacies. Trial by jury date not set yet.
2015	*United States ex rel. DiMattia et al. v. Medco Health Solutions, Inc.*, No. 13-1285 (D. Del.).	The United States alleged that Medco (now part of Express Scripts) violated the False Claims Act. In particular, it was alleged that Medco solicited remuneration from AstraZeneca in exchange for identifying Nexium as the "sole and exclusive" proton pump inhibitor on certain of Medco's prescription drug lists. As a result of this deal, Medco received reduced prices on AstraZeneca drugs: Prilosec, Toprol XL and Plendil. Medco settled the case and **agreed to pay $7.9 million** to resolve the kickback allegations.
2015	*Kmart Co. v. Catamaran Co.*, No. 2015-L-008290 (Ill. Ct. Cl.)	Kmart alleges that Catamaran "improperly manipulated prescription reimbursements." In particular, Kmart alleges that Catamaran cut payments to Kmart pharmacies and failed to reimburse Kmart for almost 28,000 pricing appeals. As a result of these pricing appeals, Kmart has **suffered $38 million in damages**. This case is ongoing.
2015	*Albert's Pharmacy, Inc. et al v. Catamaran Corporation*, Civ. No. 3:15-cv-00290-UN2 (M.D. Pa.)	Fifty-five independent pharmacies sued Catamaran for illegal conduct. The parties allege that Catamaran inflated patient costs while simultaneously underpaying pharmacies. Specifically, the pharmacies argue that Catamaran set rates below cost, made pricing data inaccessible, did not update data, and

		provided no transparency on how drugs rebates are applied. As a result of Catamaran's practices, the pharmacies' business and continued delivery of patient care are at risk. This case is ongoing.
2015	*U.S. ex rel., et al. v. Novartis Pharmaceuticals Corp.*, No. 1:11-cv-08196 (S.D. N.Y.)	The United States sued Accredo (owned by Express Scripts) claiming that Accredo recommended the drug Exjade to Medicaid patients in exchange for kickbacks from Novartis Pharmaceuticals Corp., which markets the drug. **Accredo settled the matter paying $60 million to the federal government and various states.**
2015	*John Doe v. Medco Health Solutions Inc., et al.*, Case No. 1:11-cv-00684 (D. Del.)	A relator on behalf of the United States, California, Florida and New Jersey brought a False Claims Act case against Medco. The case claims Medco (now a part of Express Scripts) defrauded state and federal health insurance programs by accepting undisclosed discounts from drug manufacturers and not passing on the savings on to its clients. This case is ongoing.
2015	*HM Compounding Services v. Express Scripts*, Case No. 14-cv-01858 (E.D. Mo.)	Express Scripts is facing an antitrust conspiracy suit in which the plaintiff a compounding pharmacy, has alleged Express Scripts engaged in a conspiracy with other major PBMs to exclude competing compounding pharmacies from their network. As a result, competition within the compounding industry has been foreclosed and consumers have been routed to the PBMs captive pharmacies. The case is ongoing, and the plaintiffs have survived a motion to dismiss.
2015	*United States v. CVS* See: http://goo.gl/Ks3FqR	CVS was forced to **pay $22 million** to resolve federal allegations that its pharmacies sold narcotic painkillers not prescribed for legitimate medical purposes.
2014	*Grasso Enterprises, LLC, et.al., v. Express Scripts, Inc.*, Case No: 4:14-cv-01932 (E.D. Mo.)	Numerous compounding pharmacies sued Express Scripts alleging that the company intentionally cut compounding spending and illegally terminated compounding pharmacies from the Express Scripts' network. This case is ongoing.
2014	*United States ex rel. Well v. CVS Caremark, Inc.*, Civil Action No. SA:11-CV-00747 (W.D. Tex.).	The United States filed a False Claims Act suit against Caremark for knowingly failing to reimburse Medicaid for prescription drug costs paid on behalf of Medicaid beneficiaries who also were eligible for drug benefits under Caremark-administered private health plans. Caremark settled the case, **paying the federal government $6 million.**
2014	*Securities and Exchange Commission v. CVS Caremark Corp.*, Civil	Stemming from 2009, CVS Caremark agreed to **pay $20 million** to settle charges brought by federal

	Action No. 14-177-ML (D.R.I.)	securities regulators that it misled investors and committed accounting violations.
2012	*Uptown Drug v. CVS Caremark*, Case No. 12-cv-6559 (N.D. Cal.)	Class of independent pharmacies filed suit against CVS Caremark alleging violations of California's unfair trade practice law by forcing maintenance prescriptions adjudicated by CVS Caremark's PBM business into CVS retail pharmacies, to the detriment of California pharmacies. The case is pending before the Ninth Circuit Court of Appeals.
2012	*In the Matter of CVS Caremark Co.*, FTC No. 112 31210	The Federal Trade Commission filed a complaint against CVS Caremark for misrepresenting the prices of certain Medicare Part D prescription drugs at CVS and Walgreens pharmacies. The misrepresentation caused seniors and disabled consumers to pay significantly more for critical medications. CVS Caremark settled, **paying refunds to 13,000 consumers for a total of $5 million.**
2009	*HHS v. CVS* See: https://goo.gl/tHlXcM	CVS agreed to **pay $2.25 million** to resolve allegations by both the Department of Health and Human Services and Federal Trade Commission that it violated the Health Insurance Portability and Accountability Act (HIPAA).
2008	*Washington v. Caremark Rx.*, No. 08-2-06098-5-SEA (Wash. Sup. Ct.)	29 attorney generals, including the Washington Attorney General, alleged that Caremark engaged in deceptive trade practices, did not inform clients of retained profits from drug switches, and improperly restocked and reshipped previously dispensed drugs. Caremark settled the matter **paying $41 million** to the states and agreed to a change in business practices.
2008	*In re Express Scripts, Inc. PBM Litigation*, No. 4:05-md-1672-HEA (E.D. Mo.)	Numerous states sued Express Scripts alleging numerous violations of consumer protections. The violations included deceptive business practices by illegally encouraging doctors to switch patients to different brand name medications and increased spreads and rebates from manufactures without passing the savings onto the plans. Express Scripts **paid $9.3 million** to settle the case, accepted restrictions on its drug switching practices, and adopted a code of professional standards.
2006	*United States of America v. Merck-Medco Managed Care L.L.C., et al.*, No.: 00-cv-737 (E.D. Pa.)	A multistate whistle blower lawsuit filed against Medco for violations of both federal and state False Claims Acts alleging defrauding the government, increasing drug prices, and failing to comply with state-mandated quality of care standards. Medco settled and **paid a total of $184.1 million**.

2005	*United States of America, et al. v. AdvancePCS, Inc.*, No. 02-cv-09236 (E.D. Pa.)	A whistleblower suit against Advanced PCS (now a part of CVS Caremark) alleged that Advanced received kickbacks from drug manufacturers, induced customers to sign contracts with the PBM, and submitted false claims. Along with a **$137.5 million in settlement**, Advanced received a five-year injunction and was forced to enter into a Corporate Integrity Agreement.

March or April 2012 4/2012

Katherine Eban

"Painful prescription: Pharmacy benefit managers make out better than their customers," Fortune Magazine

Link to original article.

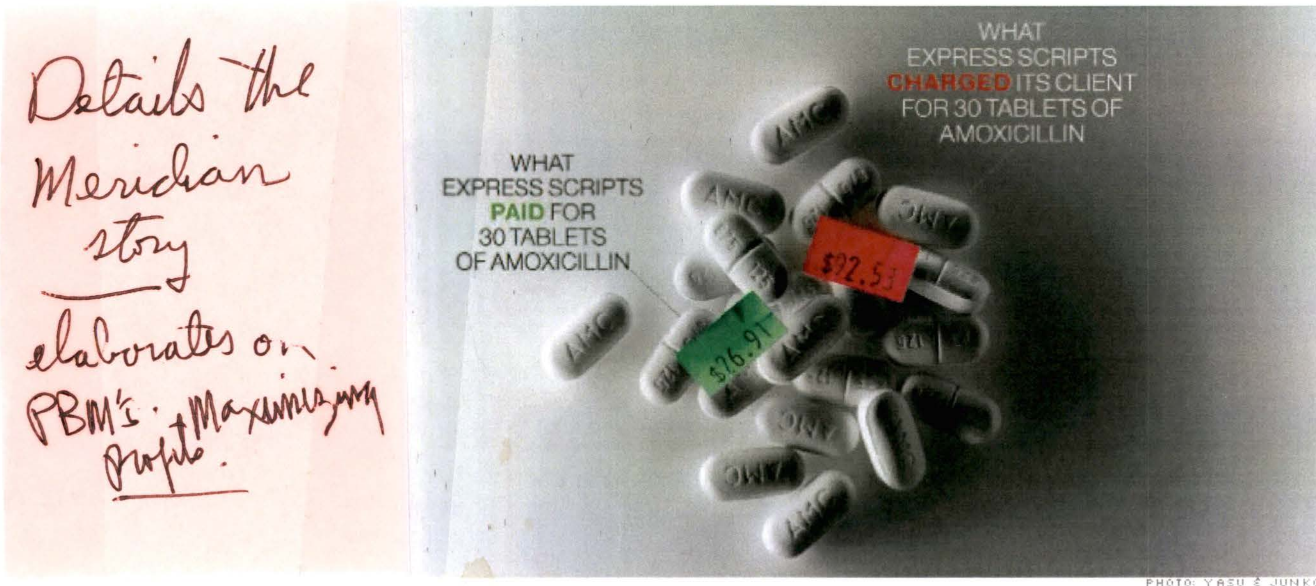

PHOTO: YASU & JUNKO

In late 2008, Meridian Health Systems, a nonprofit that owns and operates six hospitals in southern New Jersey, hired a new pharmacy benefits management (PBM) company to help reduce the surging medication costs for its 12,000 employees and their families. Express Scripts, which has since become the largest PBM in the country, projected that it would slice at least $763,000 from Meridian's $12 million in annual drug spending.

But just three months into the contract, Meridian discovered that its bills were soaring, on pace to balloon by $1.3 million in 2009. Express Scripts insisted that, in reality, Meridian was saving money.

Robert Schenk didn't buy it. He oversees Meridian's spending on medications for employees and its in-house pharmacy. Schenk, 57, had once owned two small-town drugstores but sold them in part because of relentless price-lowering pressure from PBMs. He knew firsthand how little pharmacies were paid relative to what customers were charged.

Schenk decided to figure out where Meridian's money was going and why its drug costs were escalating. That was no easy task because, like most PBM customers, Meridian received data only on what it was being charged for each employee prescription. Meridian didn't know what it cost the PBM to fill that order.

Then Schenk had a stroke of inspiration. He realized that Meridian had a second stream of data that almost no other PBM customers had: Its in-house pharmacy was paid by Express Scripts for many prescriptions. That meant Meridian could see both what the PBM was paying to buy drugs and what it was selling them for.

When he compared the two lists, the mild-mannered pharmacist was shocked: Express Scripts was making huge gross profits (known as "spreads" in the PBM world) ranging from $5 per order to many multiples of that. In one particularly extreme example, Meridian was billed $92.53 for a prescription for generic amoxicillin filled at an outside pharmacy. Meanwhile, Express Scripts paid $26.91 to Meridian's own pharmacy to fill the same prescription. That meant a spread of $65.62 on one bottle of a generic antibiotic.

Express Scripts vehemently insists it saves money for clients and that the vast majority are satisfied with its service. And like any company — to state the obvious — it's entitled to a profit. The question is, Who is making out better — the PBM or its customers? Many experts say the former. They argue that many companies stick with traditional PBMs because drug pricing is so impossible to untangle that customers have no way to verify how much they're saving, if anything.

Meridian's experience is far from unique, these experts say. PBMs effectively pad bills by $8 to $10 a prescription, according to Susan Hayes, who has audited more than 100 PBM contracts for her auditing and consulting firm Pharmacy Outcomes Specialists. As Hayes puts it, "The nation's employers are being taken for a ride."

PBMs started as paper pushers: They began hand-processing medical claims in the 1970s and evolved into middlemen who touted their ability to use corporate customers' combined purchasing power to negotiate huge discounts from pharmaceutical companies. Today the top PBMs are as big as or bigger than their clients. Express Scripts generated $94 billion in revenues last year after merging with Medco, putting it at No. 24 on the Fortune 500. Its annual profits have grown from $250 million a decade ago to $1.8 billion in the 12 months ended in June, according to S&P Capital IQ. The company now manages benefits for more than 100 million Americans.

Total industry revenues exceed $250 billion, according to J.P. Morgan analyst Lisa Gill. The big prescription managers — Express Scripts, CVS Caremark, and OptumRx control about 70% of all U.S. prescriptions — have become some of the most potent players in health care. PBMs determine where patients fill their prescriptions. They decide what drugs people will take and how much pharmacists will get reimbursed for dispensing them. They shift patients to generic drugs and require them to fill basic prescriptions at the PBMs' vast mail-order pharmacies. And with some 30 million Americans expected to gain prescription-drug coverage through the Affordable Care Act, PBM use is likely to continue increasing.

The debate as to whether traditional PBMs save money for clients has propelled the rise of a renegade group of relatively small, so-called transparent PBMs. These mostly newer competitors now account for an estimated 10% of the market.

The transparent PBMs offer a very different model. They don't profit from spreads on drugs or any secret incentives. Instead, they take a flat administrative fee for each prescription. Unlike traditional PBMs, whose contracts often bar pharmacies from revealing what the PBMs are paying them, transparent managers disclose what they pay. Most of the 500 clients of transparent PBM Envision Pharmaceutical Services (which now includes Meridian) have defected from traditional PBMs, says CEO Kevin Nagle. And independent PBM consultant Linda Cahn says all her clients have abandoned traditional providers in favor of transparent ones because "traditional contracts gouge the client."

The traditional PBMs say they provide quantifiable value. In March, Express Scripts announced that for the first time in two decades prices for routine medications dropped, declining 1.5% in 2012.

Express Scripts hailed the decrease as "the latest chapter of an ongoing success story for our utilization management programs."

Mark Merritt, CEO of the Pharmaceutical Care Management Association (PCMA), a trade group representing the 10 largest traditional PBMs, says that while "drug prices have gone up more than we'd like" over the years, his members have saved employers 25%. "We're kind of like a British civil servant," he says. "If you want to save money, tell us how much and we'll do it." Studies commissioned by his group project that over the next decade, PBMs will save employers, consumers, and the government more than $2 trillion, and have already helped reduce by a third the projected cost of the Medicare Part D program, a largely privatized drug benefit for seniors.

The PBMs' claims of cost savings are difficult to prove or disprove. Drug pricing is an almost impenetrable bog. The benchmarks the industry relies on, such as the published average wholesale price, are built on antiquated data and bear little relation to real costs. Drug companies offer undisclosed rebates to PBMs in exchange for market share. Generics are so cheap, and the prices so varied, that often the cost is whatever the PBM says it is, according to consultant Cahn.

A 2012 report by the Kaiser Family Foundation calls the PBM assertions of Medicare savings "overstated" and says the reduced cost probably stemmed from incorrectly high predictions of prices and from brand drugs going generic. Its author, Jack Hoadley, a research professor at the Health Policy Institute of Georgetown University, says, "PBMs like to say, 'We're the ones that really made that happen,' and that's partly true and partly not true. If you have a patient who's taking Lipitor two years ago, they're automatically switched to generic. In that case, the PBM doesn't do anything to create that savings." Some experts contend that prices would be falling far faster if not for hidden spreads. "If your drug prices aren't flat or going down every year, I know who's getting the money, and it should not be happening," says Craig Burridge, the recently retired executive director of the New York State Pharmacists Society. "Billions of unnecessary dollars are being added every year to the cost of prescription drugs."

At Express Scripts headquarters in St. Louis, five sprawling buildings rise from a windblown highway crossing. There the PBM manages drug benefits, dispenses medications from its mail-order pharmacy, and studies how best to manage the patients taking them. Earlier this year chief medical officer Dr. Steve Miller led the way through the blond-wood interior of the Technology and Innovation Center and up a gleaming staircase. "We now represent the interests of 100 million Americans," he says. "We are truly the voice for the payer."

Pushing open white double doors, he reveals one of the world's largest and most mechanized pharmacies. One of six distribution facilities that Express Scripts operates, it's the size of six football fields. Suspended conveyor belts traverse the cavernous space. Orange plastic bottles zip along soundlessly, then enter glass control booths, where robotic arms swing in and out.

Of the 110,000 prescriptions filled here daily only 3% require human intervention. The executives stress the benefit to patients. The pharmacy here is Six Sigma perfect, a production standard that results in about one error for every million bottles filled. At that rate, this facility will prevent about 2 million errors a year, says Miller.

That was the sort of cost-saving efficiency Meridian was looking for in 2008. For years it had seen its drug costs rise under a contract with a different PBM. Meridian executives decided to make a change and spent months looking for the right replacement.

Express Scripts seemed like a good bet. It guaranteed significant discounts on drugs and used the word "partnership" to describe the relationship. Meridian's consultant explained that Express Scripts would profit from spreads on low-cost generic drugs (though Meridian's contract with Express Scripts never specified their magnitude). But the consultant contended in an email that the PBM's profit motive would benefit Meridian: "Since they have this money at stake, they will work harder to increase the use of generics." Like the consultant, Express Scripts emphasized that its interests would be aligned with those of its customer.

That's not how it played out. Just three months after Express Scripts began handling its prescriptions, Meridian calculated that it was facing that potential increase of $1.3 million in costs in the first year alone. Meridian executives were taken aback by the PBM's response to this news. Rather than expressing sympathy or contrition, Schenk says, the Express Scripts representatives complained that the company wasn't getting enough mail-order prescriptions from Meridian. Recalls Schenk: "Their attitude was, 'Hey, you're not giving us enough business.' "

Express Scripts argued that Meridian's projections had failed to account for rising drug prices. But those estimates weren't Meridian's alone. Kathleen Boushie, Meridian's director of health and wellness, dug up Express Scripts' original presentation, in which the medications, particularly very expensive specialty drugs (such as new bio-medications and drugs for rare diseases). Boushie researched this claim and found that utilization had not increased.

In October, 10 months into the contract, Schenk asked Express Scripts for all of Meridian's specialty-drug claims. He got data for 800 claims — a total of $1.52 million, averaging $19,000 per claim. As he compared each charge with the industrywide average wholesale price (AWP), he discovered that Meridian was not getting the contractually agreed-upon discount of AWP minus 18%. Instead, it was getting AWP minus 13%, leaving Meridian with a $106,000 overcharge.

Express Scripts responds in a statement: "Because of a setup error, there was a discrepancy in how specialty medications were being billed. Once we were made aware of the error, we addressed it and made sure Meridian was being reimbursed. The situation was not typical, and the error was an anomaly."

Even as the PBM industry has grown over the past two decades, it has been dogged by state investigations, class-action suits, and allegations that the industry uses opaque contracts to maximize profits. PBMs have been accused of everything from shorting pills in mail-order prescriptions to selling patient data they didn't own to covertly shifting patients to higher-cost drugs. As a federal judge in Maine put it in 2005, PBMs "introduce a layer of fog to the market that prevents benefits providers from fully understanding how to best minimize their net prescription-drug costs."

In 2008, Express Scripts paid $9.3 million to settle a suit by New York and 28 other states that claimed it deceptively inflated costs for state employees, in part by secretly switching to higher-cost drugs, and that it allegedly pocketed millions in manufacturer rebates. Express Scripts agreed to reforms to make it more transparent. Mark Merritt of the PBM trade group says this settlement helped establish the "rules of the road" for an "emerging industry."

Five years later the battles over transparency persist. Critics say the profit centers and the "spreadsheet games," as PBM auditor Susan Hayes calls them, have changed. The PBMs' biggest profits no longer lie in maximizing rebates on brand-name drugs or shifting patients to higher-cost medication. Instead, they come from maximizing spreads on generics.

PBMs do this in a variety of ways, according to experts. Generic prices are typically set through lists of maximum allowable cost (MAC), which the PBMs establish. The PBMs may use multiple MAC lists to maximize spread, giving one set of prices to pharmacies and another to clients.

Most employers have no idea their contracts permit this. "Basically it's a 'confuse-opoly,' " says Gary Gustavson, vice president of account management for ClearScript, a transparent PBM. ClearScript was started by Fairview Health Services in St. Paul out of frustration with its experience with Express Scripts. "Buyers don't understand the PBM industry," he says, "and that's why they hire consultants — who don't understand it either."

Merritt scoffs at the notion that clients are duped or befuddled. "We only deal with large, sophisticated payers," he says, and benefits programs are "built to their specifications." He adds, "Each client gets whatever kind of transparency they want." But many people administering drug benefits don't have a clue that their contracts lack transparency. As Meridian's Boushie puts it, "I am fortunate to work with savvy pharmacists ... That secret spread that those guys understood — that was a new concept for me."

Imagine you want to buy a shirt. You go to a discount store and you see a very average shirt selling for $20 — with a tag that says MARKED DOWN 90%!!! If you know anything about discount stores (or shirts), you'll know it's inconceivable that this item ever sold for $200, or even $100. More likely, its true retail value is closer to, say, $22. But, hey, either way you get a discount, and if you're saving money, why quibble?

That, critics say, is what occurs with traditional PBMs — with one additional twist: In this instance, the discount store bought the item for $3 before selling it for $20. In this analogy, the PBM makes $17 and the customer saves $2. If that were the case, the customer might feel as if he wasn't getting a discount at all.

That's precisely what Robert Schenk came to believe once he was able to gather the data to compare what Express Scripts was charging Meridian for medications with what the PBM was paying Meridian's own pharmacy to buy them. The spread leaped out. For example, a Meridian employee filled a prescription for a five-day supply of the antibiotic azithromycin, known as a Z-Pak, at an outside retail pharmacy on Dec. 17, 2009. Express Scripts billed Meridian $26.87. The next day a patient filled an identical Z-Pak order at Meridian's pharmacy. The PBM paid the pharmacy $5.19. That meant a spread of $21.68 on just one prescription.

Schenk went down the list of drugs, finding prescriptions that matched exactly. The margins were enormous. Schenk was convinced that, as he puts it, "this has to be illegal." He was certain Meridian would report egregious fraud to state authorities. But his greater shock came when he combed through its contract. "I couldn't believe it," Schenk recalls. The contract had no restrictions on the PBM's spreads.

Express Scripts spokesperson Brian Henry says Meridian's dissatisfaction was highly unusual and adds, "When evaluating spread pricing, it's important to take into account all drugs, including the drugs where we take a loss or make only a few pennies per prescription. Again, we make money when the client saves money." Henry referred *Fortune* to a client, the Tampa Electric Co., which says it's very satisfied. Notes Brad Register, Tampa Electric's director of compensation and benefits: "I wouldn't say we've reduced cost, but we're controlling the cost of increase." Adds Henry: "Across the more than 3,500 clients who hire us (and our renewal rates are typically 95% and higher), we deliver

the savings we promise by providing solutions that drive out pharmacy waste, control costs, and improve patient outcomes."

A survey conducted by a PBM-funded industry group recently concluded otherwise. According to the 2013 Pharmacy Benefit Manager Customer Satisfaction Report, just released by the Pharmacy Benefit Management Institute, Express Scripts was ranked by its customers lowest in overall satisfaction and second to last in delivering promised savings and having no conflict-of-interest issues.

Meridian struggled to decide whether to jettison Express Scripts. Its own consultants recommended retaining the PBM, insisting that both sides' interests were "aligned." Finally, though, Schenk came across another study that confirmed his own findings. The Advisory Board Co., a consulting firm that advises medical and educational institutions on a variety of issues — including their health care spending — had completed a survey of 80 hospital members. It concluded that traditional PBMs charged 40% more than their transparent rivals.

Meridian chose Envision Pharmaceutical Services, which charges a flat fee for every prescription filled — nothing else. In the first year of Meridian's new contract, its drug bill dropped by $2 million.

Recently, transparent PBMs have gained support from another quarter. Last April the federal government added a modest transparency amendment to the Affordable Care Act. It requires PBMs managing Medicare contracts to disclose to the government the amount of rebates they are getting from manufacturers and the size of the spread.

The PBMs' trade group lobbied hard against the provision and in the end won a concession: an amendment requiring the government to keep the PBMs' incentives and spreads confidential. "We'll save you money," the industry seemed to be saying. "Just don't ever ask us how."

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Conflict of interest combining PBM's w/ pharmacies.

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PRICING POWER

Big pharmacies are dismantling the industry that keeps US drug costs even sort-of under control

Written by

Brian S. Feldman
March 17, 2016

When US lawmakers convened a hearing last month to discuss the pricing of prescription drugs, it was the testimony of Martin Shkreli—the brash former Turing Pharmaceuticals CEO who raised the price of AIDS medication by 5,000%—that garnered the headlines. But the hearing also looked at an issue that, while it got far less attention, could make drugs more expensive for far more people: almost everyone in America, in fact.

The impetus was October's announcement from Walgreens, the US's second-largest chain of pharmacies, that it was buying Rite Aid, the third. Critics said that would create a drugstore duopoly with CVS, the market leader. They didn't, however, look as hard at another effect of the deal, which likely will bring about the final collapse of the industry tasked with keeping prescription-drug costs under control. When a pharmacy owns a PBM, "it's a sweetheart deal—the two entities no longer have an incentive to negotiate with each other." Buried inside Rite Aid is a bundle of pharmacy benefit managers (PBMs). These are companies that handle the distribution of drugs for large employers, insurance companies, and government programs like Medicare. Walgreens says that acquiring Rite Aid's

PBMs would help it compete with arch-rival CVS, which controls a large and extremely profitable PBM called Caremark.

But combining pharmacies and PBMs under one roof creates a conflict of interest. It can restrict patients' access to certain prescription drugs, and can prevent independent drugstores from competing fairly for new customers.

Worst of all, it could push up drug prices. When a pharmacy owns a PBM, explains Bob Zebroski, a professor at the St. Louis College of Pharmacy, "it's a sweetheart deal—the two entities no longer have an incentive to negotiate with each other."

As the Federal Trade Commission (FTC) scrutinizes the Walgreens-Rite Aid deal, some experts believe the agency should consider more than just the potential effect on pharmacy retailing, and evaluate whether PBMs combined with pharmacies are good for patients. Indeed, there's an opportunity here: The FTC could use the review to revisit its controversial 2007 decision that let CVS acquire Caremark. That was the deal that first undermined the ability of modern PBMs to drive a hard bargain with today's giant drugstore chains.

A history of acquisition, separation, and reconsolidation

Since they were formed in 1968, PBMs have played an important role in keeping a lid on drug prices. They processed insurers' drug prescriptions, reimbursed pharmacies for those prescriptions, and maintained the formulary (the list of drugs a particular insurer deems medically safe). Most important, they used their sizable patient networks to independently negotiate lower reimbursement rates with pharmacies, and discounts with drug-makers. Being independent

meant that PBMs had an incentive to pass those savings back to their health plan sponsors, and thus, ultimately, to patients.

That's why, when drug-makers began acquiring PBMs in the 1990s, the FTC acted swiftly to undo the deals. The FTC believed that combining PBMs with pharmaceutical companies created egregious conflicts of interest. It would enable drug-makers to coordinate pricing policies, see their competitors' sensitive pricing information, and favor their own drugs over those of their competitors.

Timeline of key PBM deals

Key	Drug firm Pharmacy Pharmacy benefit managers
	Drug-maker era: Pharmaceutical firms acquire PBMs
1968	The first PBM, Pharmaceutical Card Systems (PCS), is started in Scottsdale, Arizona
1993	Merck purchases Medco for $6 billion
1994	Eli Lilly purchases PCS Health Systems for $4 billion
1994	SmithKline Beecham buys Diversified Pharmaceutical Services (from insurer UnitedHealth) for $2.3 billion
	Independent era: Pharmaceutical firms sell PBMs as a result of 1990s FTC actions
1998	Eli Lilly sells PCS Health Systems for $1.5 billion
1999	SmithKline Beecham sells Diversified Pharmaceutical Services to Express Scripts for $700 million
2003	Merck spins off Medco
	Pharmacy era: Mergers between PBMs, and of PBMs with pharmacy chains
2000	Advance Paradigm purchases PCS for $1 billion, and becomes AdvancePCS
2003	Caremark purchases AdvancePCS for $5.6 billion
2007	CVS Purchases Caremark for $26.5 billion
2012	Express Scripts merges with Medco for $29 billion (combination of largest and second-largest PBMs). Also acquires Accredo speciality pharmacy from Medco, and merges it with its CuraScript pharmacy
Feb. 2015	Rite Aid purchases EnvisionRx for $2 billion. (EnvisionRx owns a subsidiary PBM, MedTrak, which itself owns the PBMs Connect Health Solutions and Smith Premier Services)
March 2015	OptumRx purchases Catamaran for $12.8 billion (combination of third and fourth-largest PBMs)
May 2015	CVS purchases Omnicare for $12.7 billion
Oct. 2015	Walgreens announces intention to acquire Rite Aid for $17.2 billion

Today, though, it's pharmacies, rather than drug-makers, that are merging with PBMs—and the deals appear to be creating similar conflicts of interest.

In addition to CVS owning Caremark and Rite Aid owning the PBM EnvisionRx, several PBMs own smaller pharmacies. "Caremark as a PBM can give preference to CVS, and tie its products to some degree." The largest PBM, Express Scripts, for instance, owns specialty pharmacy Accredo, fertility drugstore Lynnfield Drug, and home infusion pharmacy AHG of New York.

Regardless of whether the dominant company is the PBM or the pharmacy, the problem is the same. A PBM combined with a drugstore, explains Wharton professor Patricia Danzon, has an incentive to steer plan members to its affiliated pharmacies, rather than contracting with as many drugstores as possible on the basis of location, convenience, and care for its patients. "Caremark as a PBM can give preference to CVS," she says, "and tie its products to some degree."

The numbers seem to bear this out. When the Bush-era FTC waved through CVS's acquisition of Caremark in 2007, only 12% of CVS's retail prescription revenue came from Caremark. By 2014, however, that share had tripled to 35%. In addition to being allied with the largest retail pharmacy chain, Caremark also is affiliated with CVS's Omnicare, the nation's dominant long-term care pharmacy. Another problem is that when PBMs are combined with drugstores, they lose the incentive to police against pharmaceutical company schemes to steer patients to more expensive drugs. Indeed, they may collude in them. Last year, for instance, the federal government discovered that Express Scripts was accepting kickbacks from Novartis

Pharmaceuticals to recommend the iron chelation drug Exjade to Medicaid patients, instead of a less expensive alternative. The current industry structure has "cast a complete pall over the marketplace." Express Scripts, and its specialty pharmacy Accredo, simply looked the other way.

Antitrust experts say that it can be hard to tell whether such kickbacks are offered willingly by the producer, or extorted by overly powerful retailers and drugstores. What is increasingly clear, however, is that it's the patient who pays the price. Beginning in 2012, CVS's Caremark began to use its formulary to exclude certain drugs, initially listing 30 drugs it refused to handle. Today, that number is u[illegible] and Express Scripts and OptumRx have adopted similar pra[illegible] The current industry structure has "cast a complete pall ove[illegible] marketplace," Doug Collins, a Republican representative fro[illegible] Georgia, said in an interview.

Fed gov't found ES accepting kickbacks from Novartis for expensive chelation drug

Asked whether vertical integration leads to conflicts of [illegible] anti-competitive practices, a CVS spokesperson, Erin Britt, s[illegible] our PBM, CVS/Caremark, we welcome competition; indeed, [illegible] success is predicated on thriving competition in the health c[illegible] marketplace. With over 30 different PBMs, the PBM industr[illegible] competitive."

Pity the small pharmacy

Another problem for patients is that the practice of combining drugstores with PBMs appears to be driving small independent pharmacies out of business. "We complained bitterly to the Feds and FTC about CVS owning Caremark." For patients, especially those in small towns, this means less choice as to where they can fill their

prescriptions. ("PBMs allow plans to choose to provide efficient mail-service pharmacies to members that supply home-delivered prescriptions with great accuracy and safety and at a substantial savings," said Britt, the CVS spokesperson.)

Steven Nelson, owner of Okeechobee Discount Drugs in Okeechobee, Florida says that PBMs charge independent pharmacists a variety of special fees that harm their ability to serve their customers. "We complained bitterly to the Feds and FTC about CVS owning Caremark," Nelson says.

PBMs combined with drugstores also pay independent pharmacists lower reimbursement rates for the drugs they sell, then threaten to expel the pharmacists from their network if they complain. Such threats matter, as the three largest PBMs control 78% of the market, and cover more than 180 million people in the US.

Nor is it just small pharmacies that have faced threats from PBMs; such strong-arm tactics have also been used against larger drugstore chains. Vertical integration "creates perverse incentives for PBMs to shut out independent pharmacies." Indeed, Walgreens' decision to acquire Rite Aid and its cluster of PBMs appears to stem from CVS's takeover of Caremark in 2010. Walgreens objected to Caremark's "unpredictable" reimbursement rates and practices "no longer in the best interests" of customers. For long periods of time, Walgreens couldn't fill prescriptions for patients covered by Caremark. Last November, members of the House judiciary subcommittee on regulatory reform, commercial, and antitrust law charged Caremark and Express Scripts with failing to rein in fast-rising prescription and employer health-benefit costs. Then in February, the House oversight

and government reform committee convened the hearing on prescription drug prices.

While Shkreli stole the show at that hearing, lawmakers did also talk about the problems caused by combining drugstores and PBMs. Buddy Carter, another Georgia Republican, for instance, said that such vertical integration "creates perverse incentives for PBMs to shut out independent pharmacies at the expense of the American public."

As "competition decreases," he added, "prices are going to increase. That's what we're finding now." If Walgreens successfully acquires Rite Aid and its PBMs, one of the industry's last remaining constraints on drug prices will disappear.

BUSINESS INSIDER

10/12/16

These companies you've never heard of are about to incite another massive drug price outrage

LINETTE LOPEZ
SEP. 12, 2016, 9:27 AM

ES tells clients how much they should pay but not how much things cost — when people find out, "they get very angry"

A Target store team member places an item back on the shelf near the pharmacy department at a Target store in Los Angeles, California August 18, 2009.

Reuters

It's easy to see why EpiPen has become the focus of America's fury over drug prices. It treats potentially deadly allergic reactions — for example, in a child who is stung by a bee — and its price has spiked by over 500% in a few years.

While it's easy to jump all over drugmakers, like EpiPen's maker, Mylan, other actors in the healthcare system ought to draw as much scrutiny.

One group of companies, called pharmaceutical-benefit managers, or PBMs, serve as middlemen, and they touch every part of the purchase of a prescription drug.

And now there's a growing realization, from Washington to Wall Street, that PBMs have been a big beneficiary of soaring drug prices burdening Americans — profits of the largest companies have doubled in recent years — even as they pitch their services as critical to controlling costs.

It's what one Wall Street analyst described as a "perverse incentive" in the business. A recent Morgan Stanley analysis showed that PBMs' earnings would take a direct hit if drug companies began to slow down on price hikes.

The biggest of these companies is Express Scripts, but PBM services are also provided by CVS Health, UnitedHealth Group, and several smaller companies. Because of their complexity and opacity, they've managed to dodge the kind of intense scrutiny that drugmakers are facing.

But that's changing, and it's bad news for the industry. PBMs are being sued by some customers for double-dealing, and they're now also starting to draw the attention of Congress. Perhaps the biggest threat of all: They're facing a backlash from America's largest employers, some of which are working on a way to rewire the system.

Below, we're going to try to explain how PBMs work for the more than 260 million Americans they serve, and because, unlike the other big companies, it is mostly a PBM, we're going to use Express Scripts to do this.

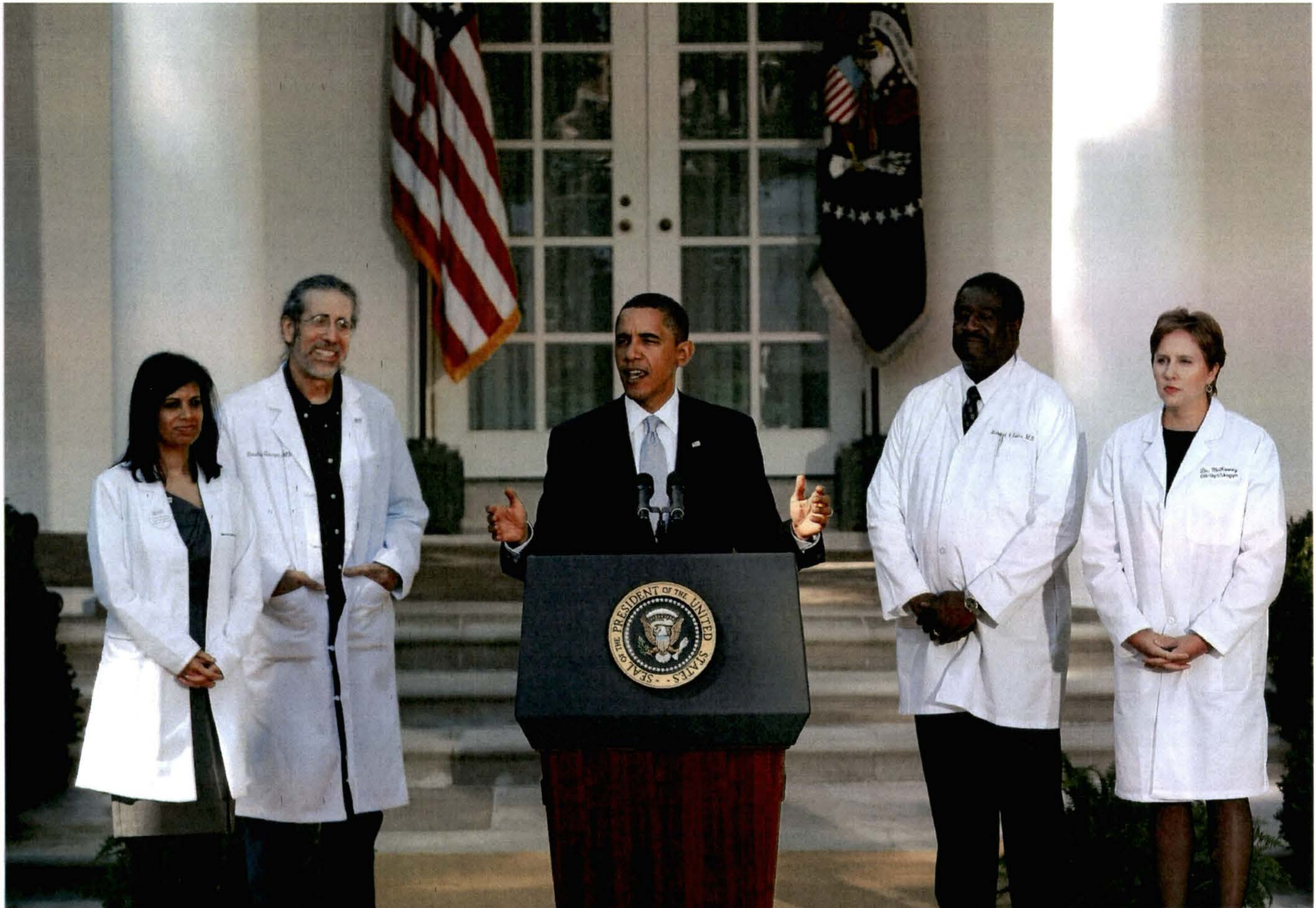
The ultimate middleman

Pharmaceutical-benefit managers started simply enough. In the 1960s, they served a need. As more Americans started taking prescription drugs, insurance companies were overwhelmed processing claims. PBMs offered to do it for them. PBMs pioneered plastic prescription cards and mail-order drug delivery.

They promised Americans they'd negotiate to keep drug prices down. They promised insurers they'd make processing prescriptions a lot cheaper and easier. And they promised drug companies they would favor certain drugs in exchange for rebates and price breaks.

They're paid fees by the insurers and employers who use their services. But they're also taking a cut of every sale. That alone isn't a problem. American business is full of middlemen, and nothing the PBMs do is illegal.

But where the PBMs are starting to get into trouble is that they're making bundles by keeping each player they deal with — pharmacies, insurers, drugmakers — partly in the dark. And those bundles, you could argue, are coming at the expense of the people who pay for healthcare.



Yes, Obamacare too.

Win McNamee/Getty Images

Here's how a PBM like Express Scripts controls information and pricing.

Let's say a doctor prescribes you a heartburn drug. Its list price is $300, but the only people who pay that are those without insurance. Because you have insurance, you go to your local pharmacy and pay a $20 co-pay. For you, that's it. Your insurer might be paying $180 for the drug as part of a large-scale agreement it came to years ago via the PBM. The pharmacy that dispenses it may get only $160 for it. That $20 difference is a spread, and that goes to your PBM as profit. That's on top of fees your insurer is paying the PBM to administer its prescription-drug program.

That's the simplest way this goes down.

All the while, the pharmacy has no idea how much your insurer is paying for the drug, and your insurer isn't exactly sure how much the pharmacy is getting for dispensing the medicine. The drug company, meanwhile, isn't even getting close to the $300 list price that makes everyone so angry.

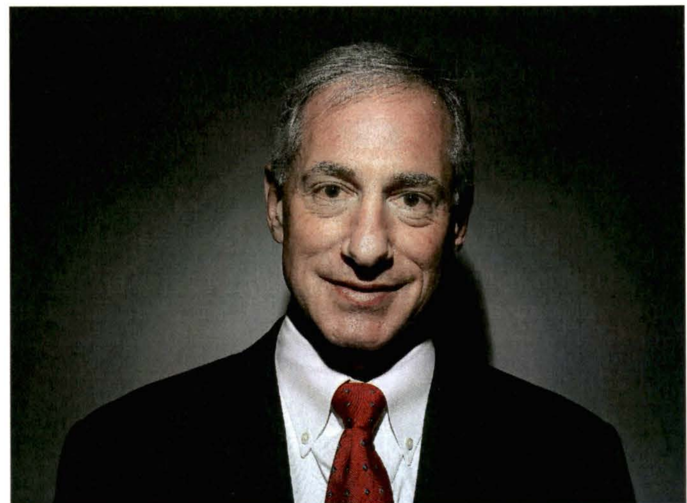
Then things get really murky.

If the price of the drug has increased, the PBM can be paid a rebate for the excess, which it pockets. The insurer, which is paying for the drug, won't know.

"These rebate amounts are less likely to be explicitly shared with a client," analysts at AllianceBernstein, an investment firm, wrote in a recent note on Express Scripts.

The note was written to answer the question of whether PBMs are "containing pharmacy costs or driving them." AllianceBernstein's answer was to put an "underperform" rating on Express Scripts' stock, warning of the risk to investors as people start to figure all this out.

'What we don't want is transparency'



Steve Miller, Express Scripts' chief medical officer.

Reuters

In the middle of the EpiPen news cycle, CNBC interviewed Steve Miller, the chief medical officer of Express Scripts.

"If she wanted to lower the price tomorrow she could," Miller said of Mylan's CEO, Heather Bresch.

He continued (emphasis added):

"We love transparency for our patients. Our patients should know exactly what they're going to pay when they go to the pharmacy counter. We love transparency for our clients — they can come in. They can audit their contracts. They know exactly what they're going to be required to pay ... **What we don't want is transparency for our competitors."**

Did you catch that?

Express Scripts will tell clients how much they should pay, but it is trying hard not to tell anyone how much things cost. The problem is that when people find out, they seem to get very angry.

'Don't you find it odd?'

In February, at a congressional hearing about drug prices, Mark Merritt, the PBMs' lobbyist in Washington, was grilled by Republican Rep. Earl "Buddy" Carter of Georgia.

Carter owns a few small pharmacies, and he was getting very angry about the lists, called formularies, that PBMs develop for their clients. A formulary is a list of drugs that patients will be reimbursed for on a given plan.

PBMs also create maximum allowable cost (MAC) lists, which tell the drug companies and pharmacies how much they'll pay for a medication. The prices on each list can be different, but only the PBM knows the difference.

"They have one list here that they're going to reimburse the dispenser at. They have another list that they're going to charge the insurance company that they're representing," Carter said at the hearing. "Don't you find that somewhat awkward? Don't you find that to be a situation where the PBM could distort the market greatly?"

Merritt said he did not.

Carter also said that PBMs have caught the ire of states because they were not updating their MAC lists frequently enough. That means that even if a drug's cost increases for a pharmacy, the PBM still won't pay more to buy the drug for its clients.

Merritt insisted that it was not accurate.

Carter countered:

> "If that's the case, don't you find it somewhat odd that [the Centers for Medicare and Medicaid Services] found it necessary to mandate ... that these MAC lists be updated every seven days, and that 26 states have passed laws requiring PBMs to update their MAC lists? ... I notice that the profits of the PBMs have increased enormously over the past few years — in fact, almost doubled. I find that very disturbing, particularly when you're talking about spread pricing."

In a statement to Business Insider, Express Scripts said, "We update [MAC lists] on a regular basis ... as need be." It would not elaborate further.

C-Span, screenshot

Side hustles

Further complicating the issue with drug companies, PBMs have entered into businesses beyond just managing lists and buying drugs. Many have their own specialty pharmacies, which are mail-order pharmacies that manage drugs that are hard to distribute. Express Scripts, for example, has a specialty pharmacy called Accredo Health.

Carter says he has adjudicated claims for customers in his pharmacy, had them rejected, and then seen the PBM call the customer right away to tell them to use its specialty pharmacy.

"A mail-order pharmacy that is owned by the PBM — now don't you find that conflict of interest? Don't you find it a conflict of interest when a PBM not only owns the pharmacy but they're reimbursing here?" he asked.

What he means is that the PBM helps to manage the drugs on the formulary and negotiates the price of the drug that it could be buying from *itself*.

Express Scripts also has a business that manages patient-assistance programs called United BioSource. Drug companies use these assistance programs to help patients get around co-pays and often point to them when drug costs go up really fast. Express Scripts picks up a management fee for doling out this cash.

While all this complex stuff is going on in the background, the *patient's* price is being held steady. In his CNBC interview, Miller bragged that patients saw their EpiPen co-pay increase from $73.03 to just $73.50.

"We're really trying to protect our plans," he said.

What it really does, though, is protect all the players from patient outrage, because rising drug prices mean rising rebates and increasing profits for the PBM.

In a research note, Morgan Stanley analysts walked through what would happen with a single product: Allergan's chronic dry-eye treatment, Restasis.

The price of Restasis has increased by double digits annually in recent years, and so has the income generated from rebates related to it. If Allergan were to cut back on price hikes, like it just pledged to, those earnings would drop by 15%.

Of course, clients such as insurers don't know exactly how much drugs cost the PBM once it has negotiated its own rebate with a drug company; clients just know how much they're paying a PBM.

Are you seeing a trend here? Whether it's from drug companies like Mylan or PBMs, real prices are just hard to come by. And because their hands are in all corners of the business — the lists that get you to customers, the assistance programs that get customers to pay, the pharmacies that can sell you the drugs — that suits PBMs just fine.

Thomson Reuters

This is your brain — this is your brain on a PBM

With a market cap of $45.7 billion, Express Scripts is the largest of the PBMs and was created as a PBM, not an insurer or a pharmacy like its two primary competitors, UnitedHealth and CVS Health. The three control most of the PBM industry.

Based in St. Louis, Express Scripts exploded in 2011 when it announced it would purchase Medco Health Solutions for $29.1 billion. In 2010, before that deal, the company's revenue was $44.97 billion. In 2015, it was $101.75 billion.

We asked Express Scripts if it thought there were any conflicts of interest in the way its business is structured, conflicts that may prompt the company to add a drug to a formulary or stock it in its pharmacy (Accredo Health), for example.

Time and time again, the company said that clients make choices and Express Scripts just gives advice.

Here are a few of the answers we got:

Linette Lopez: If the price of a drug increases, doesn't payment to your company increase as well?

Express Scripts: All individual client contracts are geared toward driving down the cost of healthcare while creating the best possible outcomes for patients. Express Scripts' performance is contingent on our ability save our clients money while ensuring that patients have access to the right medications at the best possible price with the greatest level of care.

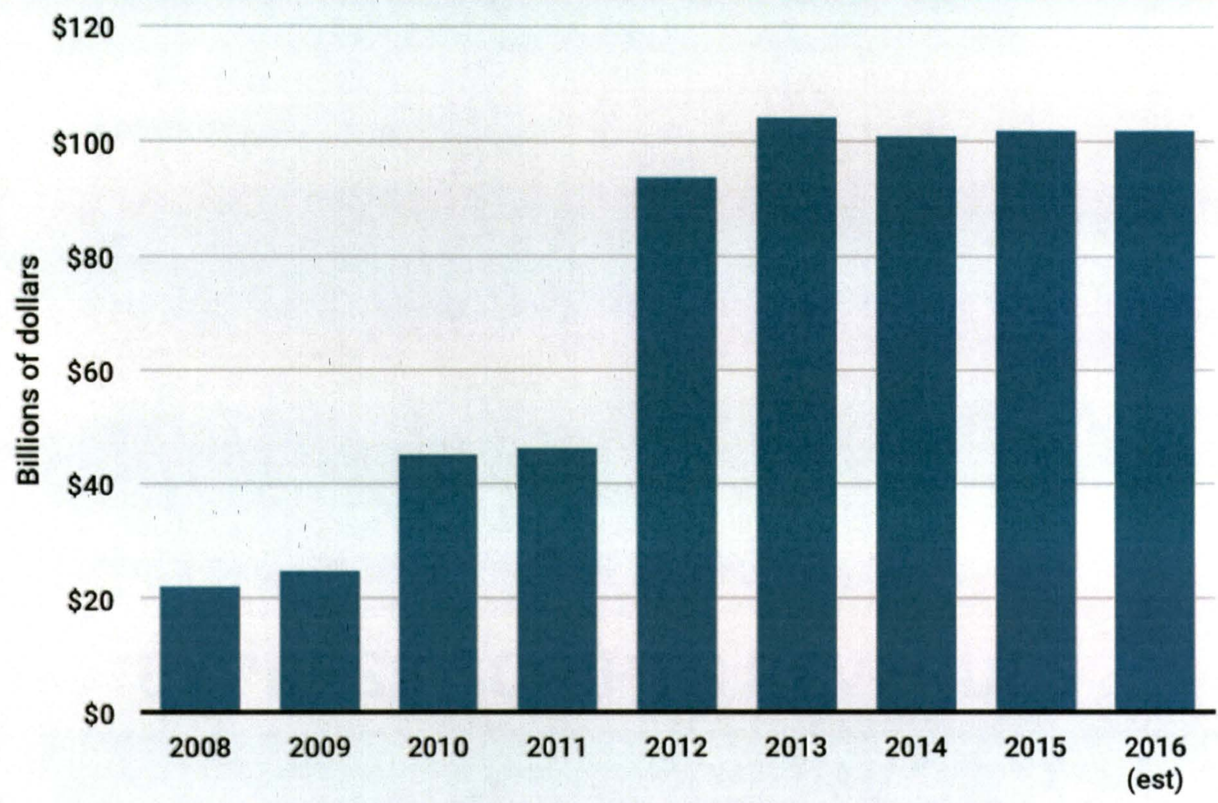
Lopez: Does Accredo sell drugs that it also provides patient-assistance programs for?

Express Scripts: Pharmaceutical manufacturers choose their PAP providers as well as their distribution channels. There are drugs dispensed by Accredo that have PAPs operated by [United BioSource]. For some

products, we determine eligibility and dispense the product, and for others the manufacturer contracts with Accredo to handle only dispensing.

Lopez: For what drug companies does United BioSource administer patient-assistance programs?

Express Scripts: [United BioSource] works with a number of manufacturers to implement PAPs to ensure that uninsured and underinsured patients who meet the qualifications of the program get access to the drugs they need. The number of companies is proprietary.



Business Insider

Dealing in the dark

What these answers reveal is that yes, sometimes Express Scripts gets paid for managing patient-assistance programs for drugs it also sells through its own pharmacy. So not only is the situation Carter described possible, patients won't even know what's going on because the patient-assistance program will mask all the cost for them.

And no, you cannot find out whom Express Scripts managing patient-assistance programs for.

And, by the way, no, Express Scripts does not "find it odd" (as Carter said) that it manages those two lists — one for what drug companies can charge and one for what clients have to pay.

"The client chooses how they would prefer to contract with us or any PBM for its service," the company told Business Insider. "Spread pricing is aligned with the payer's desire to control costs and our ability to do so. Through spread pricing, we offer lower rates and leverage our ability to secure better discounts from retail pharmacies over the life of the contract."

Many clients do not agree with this.

Earlier this year, some of America's biggest employers — including American Express, Macy's, Coca-Cola — created an organization called the Health Transformation Alliance with the aim of breaking with "existing marketplace practices that are costly, wasteful, and inefficient, all of which have resulted in employees paying higher premiums, copayments, and deductibles every year." And they have PBMs in their sights.

Here's Barron's magazine on one way they'll do this:

> "They'd do this by rewriting their pharmacy-benefit contracts to eliminate the undisclosed drug-price markups that supply much of the PBM industry's profits. Instead, the PBMs would mainly receive administrative fees, which would be significantly lower."

There's more. Express Scripts gets a significant chunk of its revenue from two clients: the Department of Defense and Anthem Insurance.

But Anthem is suing Express Scripts for breaching its 10-year contract with the company, alleging that it "failed to negotiate new pricing concessions in good faith." It's seeking $15 billion in legal damages.

A number of Anthem clients are also suing both Express Scripts and Anthem for the money they spent on overpriced healthcare.

In California, clients are suing Express Scripts for failing "to comply with statutory obligations to provide the state's clients with the results of a biannual survey of retail drug prices."

Express Scripts sent us its response to the Anthem case. Basically, it argues that it had a deal, and it accuses Anthem of being the one to violate the agreement.

The response is replete with redactions meant to protect the terms of its contract with the insurer. It's these redactions, these facts concealed by omissions, that AllianceBernstein believes puts the PBM industry in peril.

"We believe retail spread benefits from a lack of transparency and press/political investigation has the potential to reduce spread. We believe greater awareness of rebate levels or price protection rebates would increase necessary sharing with clients," the analysts wrote.

In other words, once America finds out how this business works, it's not going to like how this business works.

×

Released: March 7, 2017

3/7/17

Express Scripts
2014 $2B →
2016 $3.4B 70%↑
(Details problems)
ES + CVS = 80% of Market

Pharmacy Benefit Managers: Market Power and Lack of Transparency

Steve Pociask[1]

Pharmacy Benefit Managers (PBMs) administer prescription drug plans for sponsors (e.g., employers and insurers), negotiate drug prices with manufacturers, and negotiate reimbursement terms with pharmacies. This ConsumerGram analyzes the structure, conduct and performance of the industry and finds the lack of transparency in costs and prices leads to anticompetitive risks. The result can mean higher prescription prices for consumers.

A Market Failure

When a company hires a PBM to manage its employee prescription plan, who does the PBM represent? Typically, when a firm engages with a company to work on its behalf, it expects the hired company to act as a fiduciary, i.e., with the firm's best interest in mind. However, in some cases conflicts of interest create a *principal-agent problem*.[2] These problems can arise from a lack of transparency between the principal (the firm) and agent (the contractor). For sponsors that hire PBMs, this is indeed a problem.

While a plan sponsor faces the direct financial costs of the particular prescription plan being offered to its members or employees, only a PBM has a complete understanding of the prices and costs flowing between the various players involved in prescription plans.[3] This unique insight comes from a PBM's involvement in administering prescription plans for sponsors (and their employees and beneficiaries), and from the PBM acting as middleman in a series of opaque transactions involving sponsors, beneficiaries, pharmacies and manufacturers. These

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[1] Steve Pociask is president of the American Consumer Institute Center for Citizen Research, a 501c3 educational and research nonprofit institute. For further information, visit www.theamericanconsumer.org.

[2] Joseph E. Stiglitz, *The New Palgrave: A Dictionary of Economics*, v. 3, pp. 966–71, 1987.

[3] Allison Dabbs Garrett and Robert Garis, "Leveling the Playing Field in the Pharmacy Benefit Management Industry," *Valparaiso University Law Review*, Vol. 42, Rev. 33, 2007, pp. 33-80.

interactions among various parties create an environment for conflicts that drive PBMs to work for their self-interests, unbeknownst to the sponsor or beneficiary.

The lack of transparency leads to asymmetric market information, a *market failure*. PBMs access to better information about costs and prices gives it leverage in dealings with these other parties.[4] When there are substantial costs at stake, market failures can require regulatory and legal remedies to protect consumers.[5] The next sections will evaluate the industry structure, conduct and performance, in order to determine whether there is a presence of sustained market power that poses serious anticompetitive risks for consumers and that requires a public policy remedy.

Market Conduct and Performance

Plan sponsors hire and pay PBMs to run their prescription insurance plans and manage its costs. However, PBMs cut deals with pharmacies, promising them access to the plan's subscribers in return for cutting fees or reimbursement for what the pharmacies would normally earn for filing a prescription. This tactic, called *spread pricing*, adds additional profits for the PBMs over and above what plan sponsors pay PBMs for managing their plans. In other words, as the middleman, PBMs receive additional profit from the spread between plan sponsors payments and pharmacies' normal prices. This profiting occurs without the sponsors knowing what the various wholesale and retail prices are and without knowing the recovery of pharmacy fees.[6]

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[4] Asymmetric information always favors the party with better information. For example, say that a consumer negotiates to buy a used car. If the used car dealer has better information on the vehicle than the consumer has, then the consumer is more likely to overpay than the dealer is to undercharge.

[5] Some of the policy options are laid out and discussed by Ruth G. Thomas, "Consumer Protection, Education and Information: A Consumer Incentives Perspective," *Review of Policy Research,* Volume 2, Issue 3, p. 445-454, February 1983. Thomas analyzes policy alternatives as they impact consumer incentives in the context of different characteristics among consumers, products and market contexts. Also, see Aidan R. Vining and David L. Weimer, "Information Asymmetry Favoring Sellers: A Policy Framework," *Policy Sciences,* 21:4, 1988, p. 281. Vining and Weimer give the following guidance: "Three questions are important: first, under what conditions does the potential for significant inefficiency due to information asymmetry exist? Second, under what conditions are private responses likely to prevent the inefficiency from being realized? And third, what are the different potential, public interventions for reducing any inefficiency that does occur?"

[6] This was extensively investigated by Henry C. Eickelberg, "The Prescription Drug Supply Chain *Block Box* – How it Works and Why You Should Care," American Health Policy Institute, 2015.

In addition, PBMs establish menus and tiers of drugs available on the plan – called a *formulary*. In establishing the formulary, PBMs negotiate prices with manufacturers, sometimes promising manufacturers higher volumes of drug sales in return for lower prices or in return for promising formulary restrictions on competitive drugs through administrative steps. Essentially, PBMs limit price competition in return for deeper manufacturer discounts and rebates. However, the rebates are not necessarily known to or shared with the sponsor. The Pharmacy Benefit Manager Institute provides guidance on this practice for its members:

> *Rebates and/or negotiated price concessions from manufacturers are typically based on the predicted volume of drugs from covered lives. Additionally, price reductions (discounts) may be negotiated for including a single manufacturer's drug on the PBM's formulary and excluding competing drugs or by putting the drug on lower cost-sharing tiers.*[7]

As before, the specific terms and conditions agreed between PBMs and manufacturers are unknown to outside parties, including the pharmacies that fill the prescriptions and the plan sponsors. In other words, in addition to having plan sponsors pay PBMs for managing the plan, they profit from their dealings with drug manufacturers, as well as from squeezing pharmacies.

Prescription plans often require beneficiaries (consumers) to cost-share through copays and deductibles. These sharing provisions are typically applied to the invoice or retail price for prescriptions. In recent years, there has been an increase in invoice prices for beneficiaries, accompanied with a much faster increase in manufacturer rebates for PBMs – all unbeknownst to plan beneficiaries.[8] This means that consumers are paying more because of higher invoice prices, while PBMs are profiting more because of a surging increase in manufacturer rebates. The rebates are not flowing through to consumers in the form of lower prescription prices.

PBMs appear to be a major driver in the prescription price increases that distress consumers. As one expert writes, "most of the increase in drug spending were rebates pocketed

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[7] "Trends in Drug Benefit Design," PBMI, 2016, p. 40.

[8] Robert Goldberg, "Drug Costs Driven by Rebates," Center for Medicine in the Public Interest, http://bionj.org/wp-content/uploads/2015/11/drug-costs-driven-by-rebates.pdf.

by PBMs."[9] This flow-thru problem was also recently highlighted in a report from the Centers for Medicare and Medicaid Services.[10] Effectively, these tactics represent a tacit form of price gouging.

For example, if a manufacturer pays a PBM an incentive to offer a higher cost generic drug, by adding the drug to the plan's formulary, the sponsor's costs increase, as will the PBMs profits. This clear conflict of interest illustrates how PBMs do not necessarily represent the interest of the plan's sponsors or their subscribers. Thus, the incentive for PBMs to do what is best for the plan and consumers is in direct conflict with the PBM's incentive to profit.

There are many cases where generic drug prices are lower than plan deductibles (for example, Walmart's list of $4 generics for 30-day prescriptions). Because some plan beneficiaries do not know this and pharmacists are not permitted to disclose this information under their agreements with PBMs, consumers are paying more than they should under their plans. The practice is called *clawbacks,* and it's just one of several ways that some PBMs are increasing drug costs and lining their pockets.[11] A simple solution would be to allow pharmacists to inform consumers that they could save money by paying cash and not using their PBM plan. Once again, this illustrates that PBMs have incentives to keep prescription costs high, instead of working on behalf of the sponsors by lowering costs without sacrificing quality.

PBMs have steady sources of profit when they manage sponsors' plans: 1) beneficiaries and plan sponsors pay for the PBM for its service; 2) PBMs funnel sales to favored manufacturers in return for rebates and discounts; and 3) PBMs threaten to drop qualified pharmacies in order to squeeze concessions for prescriptions filled at pharmacies. Nowhere are the wholesale and average selling prices between the various parties published or transparent – not to drug

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[9] Goldberg, p. 2.

[10] "Medicare Part D – Direct and Indirect Remuneration," Centers for Medicare & Medicaid Services, January 19, 2017, at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html.

[11] Julie Appleby, "Filling a Prescription? You Might Be Better Off Paying Cash," CNN, June 23, 2016, at http://www.cnn.com/2016/06/23/health/prescription-drug-prices-pbm/.

manufacturers, not to consumers, not to pharmacies, and not to sponsors who offer their employees prescription plans.

It should be clear who PBMs represent. By one estimate, PBMs fail to pass $120 billion back to consumers, and retain another $30 billion in additional out-of-pocket costs.[12] Meanwhile, the market leader, Express Scripts experienced an increase in net income from $2.0 billion in 2014 to 3.4 billion in 2016 – a 70% increase in profits in just two years.[13] This comes in stark contrast with data from the Bureau of Economic Analysis showing that, across all industries, after-tax corporate profits have not increased in the last two reported years.[14] As middlemen, PBMs are making money on all sides.

Market Structure

According to the Pharmaceutical Care Management Association (PCMA), the trade group that represents the PBM industry, PBMs manage pharmacy benefits for over 253 million Americans.[15] Express Scripts (now merged with Medco), CVS Caremark and OptumRX (now merged with Catamaran) account for 78% of PBM market share.[16] Among large businesses, the top two PBMs (Express Scripts and CVS Caremark) are reported to have 80% of the PBM market share.[17] Because of recent mergers, the PBM market has increased in concentration, and that provides negotiating leverage which enables them to extract additional revenues and earnings.

Increased market concentration has allowed PBMs to become *price-makers*, and pharmacies as *price-takers.* Imagine a pharmacy working with only two PBMs in a community.

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[12] Jonathan Wilcox, "PBMs Must Put Patients First," Huffington Post, February 28, 2017, at http://www.huffingtonpost.com/entry/pbms-must-put-patients-first_us_58b60bd8e4b02f3f81e44dcc.

[13] Based on data from Yahoo Finance on March 1, 2017.

[14] See https://bea.gov/national/pdf/SNTables.pdf. Fourth quarter 2016 was not available at time of this release.

[15] Testimony of Mark Merritt, President and CEO of the Pharmaceutical Care Management Association before the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health, October 21, 2015.

[16] Health Strategies Group, "Research Agenda 2015: Pharmacy Benefit Managers," available online: http://www.healthstrategies.com/sites.default.files:PBM_Research_Agenda_PBM_RA101513.pdf. Similar figures come from "Prescription Medicines: Costs in Context," PhRMA presentation, August 2016, p. 16, available at http://phrma-docs.phrma.org/sites/default/files/pdf/prescription-medicines-costs-in-context-extended.pdf. This is similar to data published from the Drug Channels Institute, see http://www.drugchannels.net/ for more information.

[17] David A. Balto, Testimony Before the Vermont Legislative House, H. 97, February 26, 2015.

In this example, the pharmacy's access to the total market of consumers is highly restricted, since it must work through one or two PBMs to reach customers. Unless these pharmacies accept the terms of the PBMs, they are left serving a narrow cash market.

Even if pharmacies concede heavy discounts to PBMs, there is no market pressure for the PBMs to flow these savings through to sponsors or to consumers in the form of lower prices. Therefore, while PBMs benefit, consumers are not benefiting from industry concentration.

There is yet another conflict of interest. Large PBMs also provide mail-order prescriptions. If you are a customer that regularly gets drugs for a medical condition, PBMs can easily capture that customer for (typically for lower-cost) reoccurring business, thus entirely bypassing the pharmacy. In other words, PBMs can *cream-skim* customers to its own mail-order business. Because of conflicts of interest, self-dealing and the lack of transparency contributing to a market failure, PBMs have market power. For this reason, some have concluded that the PBM industry's conduct is "anticompetitive and, in some cases, plainly illegal conduct,"[18] and others are calling for industry regulation.[19]

In summary, high market concentration provides PBMs substantial negotiating power in the marketplace and raises anticompetitive risks for consumers. Based on structure, conduct and performance, there is market failure, and that failure calls for regulatory remedies to lessen PBM market power and increase market transparency.

Summary and Recommendations: Need for Transparency

After reviewing the principal-agent problem, market failures caused by asymmetric information, conflicts of interest, collusive pricing, spread pricing, price gouging, self-dealing, clawbacks, undisclosed rebates from manufacturers (including increases in manufacturer's rebates along with increases in invoice prices for beneficiaries), and establishing formularies that

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[18] Mark Meador, "Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry Through Regulations," *Annals of Health Law*, Vol. 20, 2011, pp. 77-112.

[19] Meador, at p. 111. Also see, Regina Sharlow Johnson, "PBMs: Ripe for Regulation," *Food and Drug Law Journal*, Vol. 57, 2002, pp. 323-369.

maximize profits instead of minimizing beneficiary costs – it can be concluded that PBMs are major drivers affecting higher prescription drug prices for consumers.

To the address these market failures and anticompetitive risks, as well as heighten market competition, the following public policy remedies need serious consideration:

- PBMs should provide the formulary, information on deductions and other out-of-pocket costs, and any administrative burdens (including preauthorization requirements) to consumers and employers before they sign up for a plan;
- Patients paying coinsurance and/or deductibles should pay the negotiated price and not pay the full price for drugs;[20]
- Pharmacies should to be allowed and encouraged to disclose to patients when lower cost generics or over-the-counter medications are available outside of patients' drug plans;
- Pharmacists should be allowed and encourage to disclose to patients when out-of-pocket costs are lower – if prescriptions are paid in cash instead of using insurance benefits; and
- In dealing with the flow-thru of manufacturer discounts and rebates, the U.S. Department of Health and Human Services (HRSA) or another government agency should be given federal auditing oversight to collect the information necessary to measure the extent to which PBMs are flowing (or not flowing) additional revenues back to beneficiaries. This measure of pass-thru should be made available to the public for each PBM on a macro level.

To this last point, PBMs are virtually unregulated in what is an otherwise regulated healthcare sector. Having government-run audits of PBMs – including the collection of costs and prices – would help direct PBMs in providing a quality service to beneficiaries, while minimizing plan costs for sponsors. The HRSA (or another federal agency) would maintain confidentiality of the disaggregated data, and it would retain the data in case it is needed for any future trade or antitrust investigation. Most importantly, the federal agency would make the aggregated flow-thru estimate available to the public. While this auditing oversight would be for informational

[20] The post adjudication of manufacture rebates and fees could to be determined or reasonably approximated at point-of-sale to reflect negotiated price to keep beneficiaries from overpaying a share (though copay) of inflated invoice or list prices.

purposes only, it would provide an increased level of transparency without imposing overly intrusive regulations. Consumers and sponsors would now have this information available to them when making choices about their prescription plans.

The structure, conduct and performance of the industry confirms the presence of market failures and it provides evidence that total consumer welfare is being adversely affected – consumer prices are being intentionally inflated and PBMs have a fiduciary duty to sponsors that is not being honored. The "light touch" regulatory remedies recommended here seek to reduce market power, increase transparency, provide consumers with more options, and heighten competition within the PBM market. The goal is to provide consumers and sponsors the information they need to make better market decisions.

Forbes

3/7/17

Opinion / #Regulation

MAR 7, 2017 @ 11:40 AM 5,537 VIEWS

Reform Pharmacy Benefit Managers (PBMs) To Improve Pharmaceutical Affordability

PBM's profits ↑
Patient care — nothing

Rebates going to PBM's
NOT lowering
costs for patients
or gov programs

EconoSTATS

We analyze the numbers behind economic news.

FULL BIO

Opinions expressed by Forbes Contributors are their own.

Wayne Winegarden, Contributor

Imagine if you never had to directly pay for your morning cup of coffee again. Instead, a coffee insurer guaranteed that, for a small co-pay, you could enjoy a cup of coffee every morning.

Sounds good?

The catch, and there is always a catch, is the caveat "directly pay." In this bizarre world, you would still be paying for your cup of coffee every morning, but instead of paying your favorite barista, you would now pay your local coffee insurer.

But, bureaucracy loves complexity. Instead of the coffee insurer directly paying the coffee shop, a middleman enters, promising that he can increase efficiency and reduce costs.

With the entry of the middleman, now, to receive a cup of coffee every morning, you must pay a small co-pay at the coffee shop *and* your coffee insurance premium. Your coffee insurer uses those premiums to pay the middleman, who then, after a negotiation with the coffee shop, pays the coffee vendor, kicking back a portion of any savings to the insurer.

This scheme, which sounds ridiculous and ripe for abuse, is actually how prescription medications are purchased for most Americans. Three of these middlemen, known as Pharmacy Benefit Managers (PBMs), now control prescription drug benefits for more than 260 million Americans.

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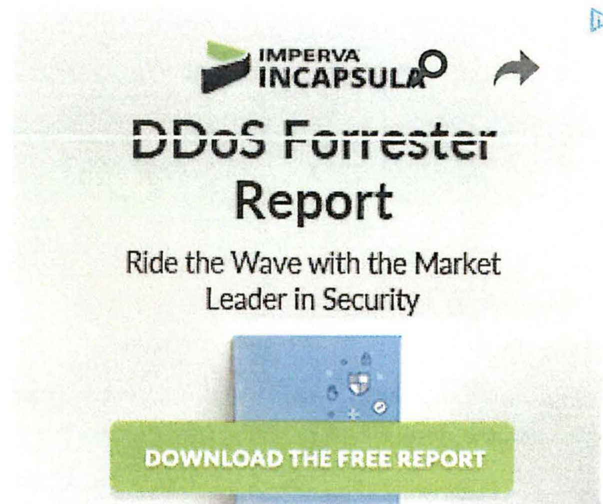

After years of quietly gaining power, PBMs are coming under heightened public and congressional scrutiny. And, for good reasons.

One reason, there is mounting evidence that PBMs price drugs arbitrarily. An analysis by Avalere Health found wide variation under Medicare Part D in generic drug prices sold on the same day, depending upon the payer (e.g. PBM). Such arbitrary pricing imposes costs on pharmacies, and the unpredictability makes it more difficult for these pharmacies to serve their customers.

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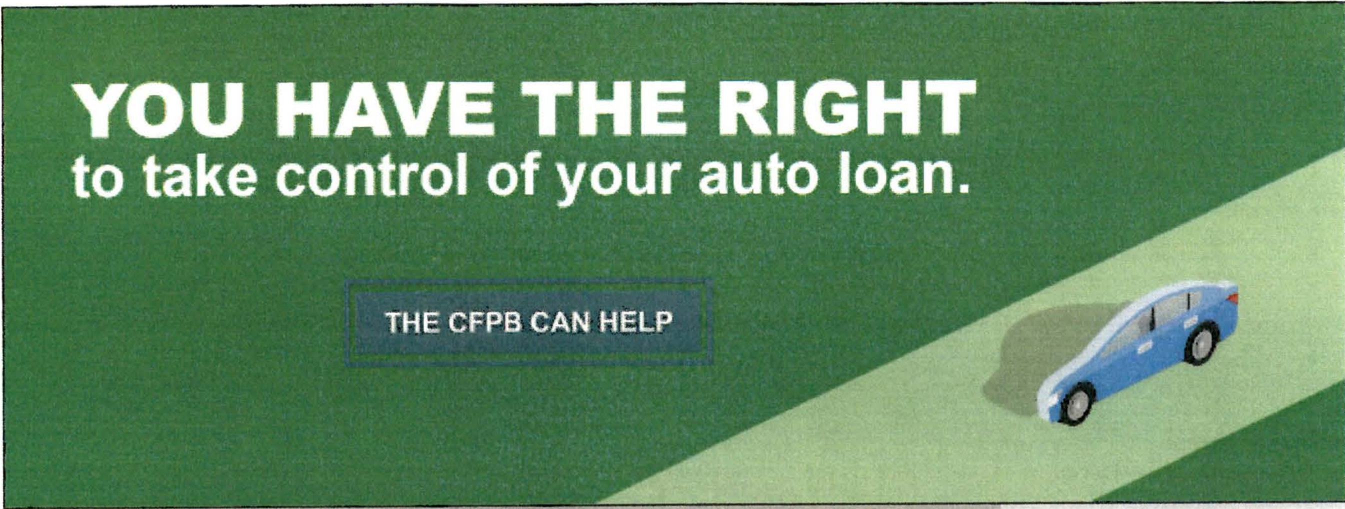

Opinion / #Regulation

MAR 7, 2017 @ 11:40 AM 5,539 VIEWS

Reform Pharmacy Benefit Managers (PBMs) To Improve Pharmaceutical Affordability

EconoSTATS

We analyze the numbers behind economic news.

FULL BIO

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Wayne Winegarden, Contributor

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Continued from page 1

Another reason is the adverse impact PBMs have on drug costs. PBMs earn revenues, in part, by charging various

fees to pharmacies. Some of these fees effectively require pharmacies to pay PBMs for the right to be compensated by the PBMs. If that sounds complicated, it's because it is.

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PBMs also earn revenues based on the difference between the manufacturer rebates and discounts and the list prices of medicines. This compensation system creates potential conflicts between a PBM's financial interests (to push the medicines with the biggest discounts and rebates) and each beneficiary receiving the best medication clinically. Since there is no PBM transparency however, there is no ability to evaluate these potential conflicts.

Relative to the total gross drug expenditures, these rebates and discounts have become quite sizable. According to a Berkeley Research Group (BRG) study, retrospective rebates and discounts accounted for 31 percent of gross expenditures on branded pharmaceuticals, or $106.4 billion, in 2015.

The total amount of revenues branded manufacturers received in 2015 was $218.6 billion, or 62.6 percent of gross expenditures on branded pharmaceuticals. The difference was earned by wholesalers and retailers.

Importantly, during a period of rising concern regarding drug costs, the manufacturer's share of total revenues has been in decline. According to the BRG study, the total branded manufacturer's share of gross branded drug expenditures fell 4.4 percentage points between 2013 and 2015.

During this same period, PBMs share of the gross branded drug expenditures grew 5.2 percentage points, more than offsetting the decline in the manufacturers' share. Put differently, PBMs' share of revenues rose at the expense of the manufacturers' who actually produce the drugs for consumers, and the pharmacies' who actually dispense the drugs to consumers. The middlemen are getting bigger and richer, while contributing nothing substantive to patient care.

These concerns were substantiated in a January, 2017 report from the Centers for Medicare & Medicaid Services (CMS). The CMS report found that the rebates that drug companies and pharmacies pay are growing, but it is the PBMs that are benefiting. The rebates are not lowering costs for patients or government health care programs.

PBM pricing vagueness also reduce the efficiency of the overall pharmaceutical market by rendering a drug's actual list price almost meaningless. As a

consequence, neither the patient nor the doctor knows how much is being spent when prescribing medications.

Broader reforms to the status quo that focus on creating a simpler, more transparent pricing structure for pharmaceuticals are necessary. However, PBMs oppose change because their current profitability is enhanced by the negotiated rebates and discounts, and from the accompanying opacity.

The good news? Congress is paying close attention.

In response to these trends, Congress is considering legislation that would improve the transparency of the fees, rebates, and costs of the PBMs. Broader health care reforms are also necessary to improve the current payment system that only Rube Goldberg could love, but greater transparency can play an important role in the meantime. The ultimate beneficiaries? Consumers and taxpayers.

Wayne Winegarden, Ph.D. is a Sr. Fellow in Business Economics at the Pacific Research Institute and Managing Editor for EconoSTATS.

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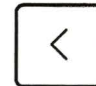

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Mar 20, 2017 4

House Industry, Business and Labor Committee
Representative George Keiser, Chairman
600 E. Boulevard Ave.
Bismarck, North Dakota 58505

Dear Committee Members,

My name is Dr. Erik Christenson, PharmD and Chief Professional Officer at Heart of America Medical Center. I oversee the Pharmacy, Physical Therapy, Occupational Therapy, Laboratory, Radiology, Respiratory Therapy and Clinical Dietary Departments at our hospital. I am writing this letter in support of SB 2301.

After completing my residency in General Hospital Pharmacy I moved to the community of Rugby, North Dakota. I have lived in this community for close to 17 years. My wife and I have raised our family in this community. My wife works at the Heart of America Medical Center. I have three children, two of which have graduated from Rugby High School and are now attending in-state universities and the third is just finishing up 6th grade. I have grow to cherish and love my community and our local healthcare system. I became the Director of the Pharmacy Department at HAMC about nine years ago and I was recently promoted to an administrative position as the Chief Professional Officer; this is in addition to my Director of Pharmacy duties. Over my tenure as Pharmacy Director, we have grown the department from a team of two employees to a pharmacy care team of 11! We provide a wide range of care to our local community including: Outpatient infusions, outpatient retail pharmacy services, long term care pharmacy, diabetic shoes, specialized compliance packaging, medication reconciliation and medication therapy management as well as many other needed services in our community. Our most recent service addition is an oncology infusion service for our patient population.

However, we are seeing a disturbing trend in the insurance industry and it is a trend that threatens the very existence of our local healthcare systems. Many insurance companies now own or have established relationships with for-profit mail order pharmacies. These pharmacies are using a variety of tactics to take all reimbursable pharmacy care away from our local communities. The insurance companies are forcing our patients to get their medications from these out of state mail order pharmacies. In our local, small hospitals we basically have four main sources of revenue. These help cover the costs of several areas of care that do not generate enough revenue to contribute to supporting the hospital system. These four areas are normally Surgery, Physical/Occupational Therapy, Radiology and Outpatient Pharmacy. Now, the insurance companies are taking away one of the revenue sources from our healthcare systems. This could irreparably harm our local, community-based healthcare systems and prevent us from having the resources needed to provide quality care to our patients and communities.

In a community such as Rugby with a population of about 3,000 our healthcare system is the major employer in town with approximately 389 employees. So, not only do these practices by out of state for-profit companies hurt our patients by decreasing our resources, these practices also threaten the very existence of our communities as we know them.

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I do not want to take up too much of your time so I will provide a summary of the issues at hand and then close with why this Bill is beneficial to North Dakota and its communities.

Issues at hand:

1. **These companies are harming our patients.** By not allowing our patients to utilize their local healthcare providers and pharmacies, the Pharmacy Benefit Managers (PBMs) and the pharmacies they own or have relationships with are creating situations that could lead to potential patient harm. I have dealt with multiple situations of potential or actual harm to patients because of noncompliance with medications, improper storage of medications or lack of professional guidance on the use of medications. These situations can be directly linked to the mail order practices of out of state pharmacies. Mail order is not a good model for patient care and safety. I am constantly working with patients that have problems with their mail order medications. Patients have trouble reaching anyone at the mail order pharmacy that can help them when they have questions, they do not receive their mediations on time and at times they don't know why they were sent a certain medication. Patients do not have anyone conveniently available in the pharmacy to discussion their questions or concerns regarding their medications.
2. **These companies are not driven by healthcare professionals, but by for-profit motives.** Do not allow these for-profit companies to remove healthcare access from our rural communities. We need to empower our local health professionals to provide care. Our health professionals have taken an oath to care for our patients according to the best care standards available. We have too many examples of large, for-profit corporations putting aside the health and well being of our citizens for the almighty dollar.
3. **These companies say they will save our businesses money. However, our healthcare system utilized one of these large PBMs and we were never shown the savings given to our hospital or our employees.** Our premiums have continued to go up and our deductibles have continued to increase. The PBM will not show us how much they are actually paying the mail order pharmacies and how much they are charging us to manage our pharmacy benefit. This practice of "spread pricing" is one way many of these PBMs are making huge profits at the expense of our patients. Our facility has also seen firsthand that the hospital's prescription benefit plan is charged essentially the same amount for the prescription whether it is filled locally or at the out of state mail order pharmacy. So I ask you, where are the savings? If the PBMs are supposed to be saving the consumer money as well as cutting costs, how are they making record profits? Express Scripts alone made over $100 billion last year! How do they afford all of these lobbyists that fly into our state to take away our healthcare? The cost of prescription drugs continues to sky rocket and yet our local pharmacies are making less and less every year. The money is obviously going somewhere other than to our local pharmacies. There is mounting evidence that these drug "middle men" or the PBMs are taking a large amount of the profits. Not only do they take our resources, they also increase the costs of providing care because of all the mediation misadventure caused by the mail order system.

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4. **These practices are costing our local healthcare systems hundreds of thousands of dollars.** Our 340B drug pricing program provides Heart of America Medical Center with about $700,000 annually. We use this revenue to keep our ER open and operational, provide diabetic education specialist services and operate a local paramedic/ambulance service; all of which would not be possible without these types of funds. However, these funds only come from prescription utilization at a local outpatient pharmacy, whether hospital or retail based. We do not receive these funds if an out of state mail order pharmacy fills our patient's prescriptions. It is also noteworthy that 340B funding is best for "specialty" medications. However, the push by PBMs to use out of state for-profit pharmacies is taking away those much needed funds/ revenue from our local communities. Our facility has tried to contract with one of these PBM owned mail order pharmacies to no avail. They will not work with us, most likely because we are too small.
5. **If we allow the out of state pharmacies to take all of the resources out of our communities, not only will we not have access to local quality healthcare services as we do now, we will also not be able to employ many of the professionals we need.** What does it matter to our employees and community if the PBMs save us a few dollars here and there if in the end we lose hundreds of thousands of dollars every year in revenue to our local community and our jobs? If we lose our local healthcare services and facilities along with our healthcare professionals, we will also eventually lose our communities.

Again, this is just a sampling of the issues PBMs are causing for healthcare delivery in our small rural communities. SB 2301 will go a long way to help stop these abuses and diversion of resource from our communities. I urge you to pass SB 2301 and help save our rural communities in North Dakota.

Erik Christenson, PharmD
Chief Professional Officer
Heart of America Medical Center
800 S. Main Ave
Rugby, ND 58368

Mar 20, 2017

ND House of Representatives Industry, Business and Labor committee:

RE: SB2301

Mr. Chairman and members of the committee.

My name is David Olig. I am a pharmacist and pharmacy owner from Fargo. I am currently serving as the President of the ND Pharmacy Service Corp., a wholly owned subsidiary of the ND Pharmacists Association and am a former member of the ND Board of Pharmacy.

Hopefully to prevent duplication in testimony, I have decided to address one aspect of the bill before us this morning. That is Item number 5. " A licensed pharmacy or pharmacist may dispense any and all drugs allowed under that license."

I will assume that most everyone on the committee operates under the premise that fewer rules and laws that encumber the business and professional sector while still maintaining a safe clinical environment is a position to strive for.

I think it is safe to say that the practice of pharmacy in ND is very aptly regulated by the ND Board of Pharmacy. If you have time and are so inclined I would ask that you read the NDBOP mission statement. I can assure you from my experience serving on that board that they take it very seriously. It addresses professional competence, ethics and service and the recognition that pharmacy and pharmacists are seen as a primary health care providers capable of responding to society's health care needs.

That being said, the current practice by the claim paying PBM's to require one if not two specialty pharmacy accreditations is nothing more than an extremely expensive and restrictive tax and roadblock to the delivery of these medications to our patients here in North Dakota. In preparing my testimony I reached out to URAC one of the supposedly acceptable accrediting agencies. URAC is an organization founded primarily by the insurance industry for the insurance industry. I was told by their staff that to have our Southpointe Pharmacy in Fargo accredited is would take 10-12 months and would cost $71,826.00 for a 3 year accreditation. The documentation for this application is 250 pages long.

There is another accrediting agency, Center for Pharmacy Practice Accreditation, (CPPA) that was started by national pharmacy organizations, APHA, ASHP, NABP among others in the industry that also determined their own accrediting standards. Although less expensive it is still an onerous task that takes months to complete and costs thousands of dollars and must be repeated every 3 years. I am now finding that the PBM's will NOT ACCEPT this accrediting standard for inclusion in their provider networks. It is apparent by this that it is not the premise of accreditation leading to excellence, if in fact it does, but rather the roadblocks being put up by the PBM's. I am finding that today many PBM's are requiring accreditation from TWO organizations. Those that they choose.

The obvious goal of this accreditation standard is to make it so difficult and expensive that most pharmacies in the country will not be able or willing to participate while at the same time forcing patients to have their specialty meds filled at their mail order pharmacies. This model looks nothing like a free market and is in fact extremely anticompetitive which can only lead to higher costs. The extreme lack of transparency in the PBM's current models continues to facilitate the very rapid increase in pharmaceutical costs. MANY non PBM sponsored studies have already verified this.

Even obtaining this accreditation by one or more of these organizations, as is now required by many PBM's, does not guarantee the pharmacy and its patients access to the medications that have arbitrarily been placed on their specialty pharmacy products list. A list that the PBM originates and maintains at its own pleasure. We are now being told of closed networks that do not allow even credentialed pharmacies, that are not the PBM owned mail order pharmacy, not being allowed to serve their patients needing these medications. Follow the money.

You will hear that this bill will lead to higher costs to plans and plan sponsors but I can't imagine how. The pharmacists of North Dakota are not asking to be paid more, only to have access to the medications and the ability to dispense these medications to our patients here in North Dakota. The lack of transparency and the PBM's standard of practice in rebates and spread pricing have MUCH more to do with increasing medication costs than any other aspect of the pharmaceutical delivery system. Numerous studies, not written and funded by the PBM owned PCMA have shown this to be true.

Please let me share with you the criteria supposedly necessary for medications to be included on a specialty pharmacy list. This is taken from CPPA's documents.

1. **Typically high cost (greater than $600/mo.).** Thanks to PBM driven rebate and formulary restrictive practices, think EpiPen and Insulin products as a model as well as most new products, many medications fall into that category today.
2. **Involve complex treatment regimens that require ongoing clinical motoring and patient education.** Such as: congestive heart failure, thyroid disease, fertility medications, diabetes etc. as well as the new biologics. All of which we have been successfully treating since before PBM's existed or the products were introduced.
3. **Have special handing, storage, or delivery requirements**. Pharmacies in ND properly store hundreds of drugs every day. We all have refrigerators that are verified by the NDBOP. We correctly dispense and deliver 10's of thousands of prescriptions daily. As far as delivery goes, the mandate to mail order pharmacy for these products leads to a substandard form of care resulting in restricted if any patient consultation/contact and constant problem of having medications either not being delivered on time, being frozen or cooked on the patient's front step after being delivered by the mail man. We get reports of this at least weekly. Who pays for this waste???
4. **Are generally biologically derived and available in injectable, infusible, or oral form.** Many medications are biologically derived: insulins, fertility meds, hormone replacement. The derivation has nothing to do with safe delivery of medications. Meds that require infusion do require special care and should be dispensed and administered at an infusion facility if the patient is unable or unwilling to do it themselves or it is necessary based on the medication that his being administered. Many of the medications on the product list have been available since I began dispensing medications 42 years ago. Many have also been around long enough to become generics.
5. **Are dispensed to treat individuals with chronic and/or rare diseases.** Really..... What is it these people think we do all day? I find this professionally insulting.
6. **Frequently have limited or exclusive product availability and distribution.** This limited distribution can be the result of necessary pharmacist education. These scenarios have been around for years and present typical day to day scenarios to comply. On the other hand when PBM owned mail order specialty pharmacy sign exclusive distribution contracts our patients do

have limited availability. Also is happening daily. Follow the money... This can only add to costs.

7. **Treat therapeutic categories such as oncology, autoimmune/immune, or inflammatory conditions marked by long-term or sever symptoms, side effect or increased fatality.** Again what do they think we do every day.

All of this being said I must absolutely acknowledge that there are many challenges associated with the proper dispensing of a number of the new medications that are being released. It is imperative that the pharmacist responsible for delivering these medications to the patients that need them are professionally prepared and competent to dispense them. Again that responsibility lies with the pharmacist and the only true regulatory agency in ND the NDBOP. Not the claims payer that owns the mail order pharmacy that patients are required to use.

Only in our industry do we have the scenario where: The insurance company owns the PBM that owns the mail order pharmacy and specialty pharmacy and contracts with pharmacy providers that THEY are in DIRECT COMPETITION WITH. OR our pharmacy competitor (CVS/Caremark) owns their own retail pharmacies, their own PBM and mail order/specialty pharmacy and also contracts with pharmacies to provide. This may well be the most anticompetitive marketplace model in the nation. NOTHING about this portrays a free trade model.

In closing, accreditation does not guaranteed competence or excellence. Professional diligence and dedication to patient care do. Those attributes must be put into place by the pharmacist who has the relationship with their patient. Pharmacists must be given the choice to provide the medications to their patients that they feel competent to provide. This oversight must be maintained by the NDBOP and not the claims paying PBM who has a huge financial incentive to restrict access to these medications to our patients.

The current model put forth by the PBM's guarantees higher costs to providers, and more than likely to plan sponsors, due to lack of transparency, and limited distribution scenarios. Limited access to pharmaceuticals to patients and pharmacies and, substandard delivery of pharmacy services by mail order to patients. The NDBOP was recently asked to relax their patient consultation standards because they "did not fit the mail order pharmacy business model".

Please support SB 2301

Thank You,

David Olig, R.Ph.

Mar 20, 2017

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House Industry, Business and Labor Committee
Representative George Keiser, Chairman
600 E. Boulevard Ave.
Bismarck, North Dakota 58505

Dear Chairman Keiser and Committee Members,

My name is Patrick J. Branco. I am in full support of Senate Bill 2301. I am the CEO at Heart of America Medical Center in Rugby. We are a 25-bed Critical Access Hospital, 60-bed Skilled Nursing Facility, 63-bed Basic Care Facility, and a 40-bed Assisted Living Center. We are responsible for the health care of a large number of patients in our small community. We are situated over 60 miles from the nearest tertiary care facility and 150 miles from the nearest quaternary care facility. Our frontier setting requires us to be highly capable and provide care of the highest quality.

With the reductions in reimbursement for services in the health care world it has become imperative that rural and frontier Hospitals become expert in managing costs and making limited revenue stretch across multiple services for the benefit of our communities. Any further erosion of revenues will almost certainly lead to a reduction in services and staff and could ultimately degrade the quality of life in our rural communities. Among the many services we provide only a small handful produce a positive revenue benefit to the Hospital to fund all of our services. These handful include surgery, pharmacy, OT/PT, and radiology. All of the other services are necessary but are poorly reimbursed or in many cases operate at a significant loss.

Mark Twain famously said there are "lies, damned lies, and statistics". I agree but I would add a forth and it is "deception". This deception here is that if a story based upon a myth is repeated often enough the people begin to accept it as fact and it has the ring of truth. We are dealing with one of those deceptions here with the myth that taking one of the few revenue-producing operations out of a community and endorsing a mail-order pharmacy system will save money and improve care. This is a myth, and a lie, and a damned lie supported with false statistics. Our insurance companies are purchasing pharmacies for the purpose of enhancing their revenue by controlling not only the premium dollar but the retail sales dollar as well. Stripping away the ability of the local pharmacy to deliver personally-focused care from a knowledge base to our patients critical to the medication treatment cycle. Every nurse learns the 5 "Rs" of right patient, right medication, right time, right dose, and the right route. A mail-order system assumes four out of the five "Rs" will be met by the patient. This causes me to question the safety. In my personal history with mail order pharmacy contracted by the VA I have experienced potentially deadly errors. Once every 3 months I receive an extremely expensive injectable medication. It comes pre-loaded in a syringe with instructions. On 3 occasions I have

received the syringe with the instructions from the pharmacy stated in bold letters **GIVE INTRAMUSCULARLY ONLY**. The syringe itself is labeled for subcutaneous use only and the medication insert also says that this medication should only be given subcutaneously. I chose to ignore the mail-order pharmacy advice and gave the medication subcutaneously as required. I notified the pharmacy and the same error was committed two more times. Finally the route of administration was corrected on my subsequent dose but the package was delivered to my doorstep in July without notifying me and I was out of town. The refrigerated medication sat in its' Styrofoam container for 8 days in 100+ degree weather. This medication is over $5,000/dose. Is this cost effective? And by the way I did not administer the medication to myself!

Mail-order pharmacies pretend to offer reduced cost pharmaceuticals delivered safely and expeditiously. This is an unproven myth. I know of many cases of wrong meds shipped to wrong patients in the wrong doses exposed to weather and theft and with no savings in cost. My story is just one.

Please do not allow insurance companies to take away our ability to practice safe and cost-effective health care locally in our town and in our State. The very survival of our small rural and frontier hospitals rely on this source of revenue and our patients survival rely on the highly qualified pharmacists personally invested in their safety.

Please support this bill.

Thank you most sincerely,

Patrick J. Branco
CEO

George Keiser

Chairman of the House Industry, Business, and Labor Committee

Dear Committee Members,

My name is Dustin Hager. I am a lifelong rural North Dakota resident. I was born in Williston during the 1980s oil boom. I attended all of my schooling here in North Dakota, including earning an associate's degree from Bismarck State College in paramedic technology, a Bachelors of Applied Management from Minot State University, a Masters of Business Administration from the University of Mary and a Masters of Physician Assistant Studies from the University of North Dakota. I have committed myself to rural health care and when the trend was to leave North Dakota I bucked that trend and remained here to help care for rural North Dakotans. Currently I am a Physician Assistant at the Heart of America Medical Center in Rugby, ND. I serve as the Chief Medical Officer along with the duties of clinic manager. In addition to those duties I serve as the Medical Director of the Heart of America Corrections and Treatment Center in Rugby, ND.

Today I am here to provide testimony in favor of SB2301. As many of you are well aware this nation has a rural health crisis. Seventy-eight rural hospitals have closed since 2010[1]. Right now, 673 additional facilities are vulnerable and could close—this represents over 1/3 of rural hospitals. North Dakota hospitals are not immune from this. Our facilities operate on slim margins that only seem to be getting slimmer. Many companies are engaged in business in the healthcare realm, one that has proven to be lucrative for them; however, it often comes at the expense of our local hospitals.

SB2301 would help to address one of those concerns. This bill will allow our local pharmacies to dispense specialty medications. Under the current system, if I have a patient that requires a specialty medication the PBM will force them to use a mail order pharmacy, all of which are out of state. The PBMs take away consumer choice. In many industries when you limit consumer choice you limit competition and drive up costs. PBMs require patients to obtain services from their pharmacy; interestingly many of these PBMs also own the specialty pharmacies that they require the customer to utilize. Our local pharmacy could obtain these medications under the 340b program, which would generate significant revenue to our local facilities, which further helps to provide additional services to patients. Our own facility has utilized these dollars to expand services, such as diabetic education, EMS, and allowed for upgrades in systems such as our MRI and CT units. Cut these margins further and more rural facilities will be vulnerable and could close.

I myself utilize one of these specialty medications. I am insured with the largest insurer in the state. I have rheumatoid arthritis. I am currently being treated with Enbrel. My insurance company requires that I obtain my medication through their pharmacy and not a local pharmacy where I obtain my other medications. This pharmacy is not located in North Dakota. My prescription is then sent to me via

delivery. I have had one occasion where my medication did not show up in time, despite being ordered two weeks prior to when I needed it. My medication did arrive nearly 5 days late. I was not able to take my medication as my doctor had prescribed. This meant that I went 5 days without any medication to control my condition. My story is not alone. I have multiple patients that have had the same issues. Imagine waiting for your medication to control your condition during a North Dakota blizzard. Our local pharmacy is often left to field calls from these patients pleading for assistance with their medication. Looking out for our patients, our pharmacists will sit down with them and assist in any way they can, however not being able to dispense these medications means they are providing these services for free. A quote in a recent Forbes article stated it best "Put differently, PBMs' share of revenues rose at the expense of the manufacturers' who actually produce the drugs for consumers, and the pharmacies' who actually dispense the drugs to consumers. The middlemen are getting bigger and richer, while contributing nothing substantive to patient care." [2]

I urge you to support SB2301 and vote yes!

Dustin Hager, PA-C, MBA

Chief Medical Officer

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1- http://www.shepscenter.unc.edu/programs-projects/rural-health/
2- https://www.forbes.com/sites/econostats/2017/03/07/reform-pharmacy-benefit-managers-pbms-to-improve-pharmaceutical-affordability/2/#1f1995fc7494

SB 2301

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Testimony for Public Hearing
Industry, Business, and Labor
March 20th, 2017
Tallie Schneider

S.B. No. 2301 (Industry, Business, and Labor) – Specialty Pharmacy

My husband and I have struggled with infertility since we decided we wanted a baby after we got married in June 2008. The first couple years we didn't really stress over it since I was still finishing up my college degree. We somehow conceived without medical intervention the summer of 2011, after 3 years of not preventing a pregnancy. The pregnancy resulted in the birth of our only child, a boy named Camden, in April 2012. After Camden turned 1 year old we decided to no longer prevent pregnancy again the summer of 2013, knowing that it had taken us some time to conceive Camden. I used at home ovulation kits to help determine ovulation and we became pregnant again around March 2014, just shy of trying for a year. At 8 weeks pregnant I began spotting so I went in for an ultrasound and a heartbeat was confirmed. Since I was not experiencing cramping and the baby had a heartbeat, we did not get overly concerned. Two days following my ultrasound, I lost the baby. Since the pregnancy that resulted in a miscarriage, it has been a long, stressful journey for us.

I decided to seek medical treatment for our infertility. I received an official diagnosis and began infertility medications. I again became pregnant from oral infertility medications and a shot to induce ovulation, only to lose the baby again the week after getting a positive pregnancy test. I was devastated. It took so long to even conceive and then to not be able to maintain a pregnancy only added to the frustration and heartbreak.

I sought out a second opinion following the two miscarriages that happened in a row to determine if there were other factors contributing to why I couldn't maintain a pregnancy. After switching clinics we continued to use medications to help with the infertility. One of these was a subcutaneous shot that induces ovulation and is based on results of an ultrasound. This shot is given at a very specific time and is usually given the night of the ultrasound unless the ultrasound results indicate otherwise. This system worked fine for awhile. I was able to have some of my ultrasounds in Rugby and some of them I traveled down to Bismarck. I would get my results and then if needed, go pick up my shot at my local pharmacy in Rugby. Then in the spring of 2016 I received a letter from my insurance company stating that a medication I was receiving was considered to be a specialty medication and I would no longer be able to get it at my pharmacy. There were several options listed in North Dakota, none of which was my pharmacy that I fill at, and mostly mail order or out of state pharmacies. After this change, I ended up having to pay cash at my local pharmacy due to immediate need of the medication. The next time I was able to pick it up at a pharmacy in Bismarck that I randomly picked off of BCBS's list. This was a huge inconvenience for me since not all of my ultrasounds were done in Bismarck. I also didn't want to spend the money on the medication and order ahead of time from a mail order pharmacy, only to get ultrasounds results indicating that I didn't need the medication, especially when insurance money spent on infertility services has a lifetime maximum that doesn't take much to meet. So this was my first

experience with so called "specialty" pharmacy. Hugely inconvenient to me and at a higher expense to me due to my pharmacy not being able to bill for a medication that I needed.

My next experience once again came at an additional wasted cost to me. My husband and I ended up going through IVF this past November and again in January. Even though I did not want to resort to mail order pharmacy for all of my medications, I was left without much choice. The first round of IVF, I ordered all of my medications through Prime Therapeutics Specialty Pharmacy, the pharmacy associated with my BCBS plan. I received all of my medication in a timely and appropriate manner. I actually thought to myself, ok that wasn't all that bad. Well, what I didn't realize is that the whole course of medication can change and is all based on my personal response which is measured with labs and ultrasounds. However, since I didn't have the option to pick up my meds locally following my lab and ultrasound, I had to make sure I had enough medication on hand and have it ordered ahead of time. This resulted in me having multiple excess medications on hand and essentially wasting money of insurance benefit I had toward infertility services that could have been used for other services. I still have approximately $1000.00 worth of medications from the IVF cycle sitting at my house that I ended up not needed. Since I used up all of my lifetime maximum of $20,000 infertility benefit, that additional $1000 would have been really nice to go toward the procedure instead of wasted medication.

My 3rd experience was even worse and could have been very detrimental. Since our first cycle of IVF did not work, we decided to proceed with a frozen embryo transfer. I did not need a lot of medications for this cycle which was a relief. Once again, the one that I did need required some lab and ultrasound monitoring with dose adjustments made based on the results. I called to order from Prime Therapeutics Specialty Pharmacy at the end of December. They proceeded to tell me that they were out of stock and they would put an override in place for me to get it at my local pharmacy. This worked out great! As our cycle proceeded, it seemed like I was going to need more medication. I did the math and I would have enough to get me through until the exact day of my ultrasound. My medication outline indicated that I would need two doses beyond my ultrasound date. As much as I did not want to order a medication just for two additional doses, I was left with no choice because I couldn't risk the chance of ruining the cycle. This medication had an out of pocket cost to me of $630 and I didn't even know if I would need it for sure. Once again, if I would have been able to pick this up at my normal pharmacy, I could have waited until I was completely out of medication to go in and pick up more so that none would go to waste. I called Prime Therapeutics Specialty on Monday January 9th. I had been told in the past that as long as I called before 5PM EST that I would received the medication next day. Well the patient care specialist that I talked to that day indicated that it wouldn't ship out until Tuesday and would arrive on Wednesday. I figured this would still work out since I wouldn't need a dose until Thursday morning. I received an automated phone call Wednesday morning stating that I had a package that was going to be delivered that day. When I got home from work that evening, there was no package at my door. I waited all evening, knowing that sometimes the UPS driver delivers late. I finally called into Prime Therapeutics at 9:45. They proceeded to tell me that the driver technically had until 11 PM to make the delivery. I went to bed, knowing that my dog would wake me if he did deliver that evening. The next morning, there was still no package. I called Prime Therapeutics right away Thursday morning to get a tracking number and information on where the package was. I was very concerned

because the temps that week had highs in the negative degrees and this was a liquid injectable medication. After over 30 minutes on the phone I was given a tracking number and told that the package was delayed one day and would be arriving later Thursday afternoon. The package was delivered at 7:08 PM on Thursday January 12th, 2017 and was completely frozen. It was not packaged in any special type of packaging, simply a cardboard box. It also had the wrong directions on it due to them filling the prescription from my first IVF cycle instead of the new prescription from my second cycle which are two completely different processes and doses. I called Prime Therapeutics once again to receive directions on how to proceed. They were not able to give me an answer but told me that they would have a pharmacist call me back to talk to me about it. I had a pharmacist finally call me back an hour later. I was instructed that the medication was no longer stable to be used. I was instructed to call Prime Therapeutics back yet again the next morning because there was nothing more he could do for me to get the medication or for me to get refunded for the damaged medication. He told me that he made notes in my account as to what had happened and they would be able to help me the next morning during normal business hours. I went to bed, hoping that I enough left in my current vial to squeeze out for my morning dose.

I called Prime Therapeutics again the following day for instruction on how to proceed with returning the medication, getting and refund, and getting the medication locally as I would need it immediately. Luckily I had been proactive with my local pharmacy and asked them to make sure they had it on hand for me in case the delivery had been delayed again. They had been given an override to bill before so I was hoping that they could again. I spent 46 minutes with them on the phone, over what should have been my lunch break. When I called, there was nothing in my account indicating what had happened. I got asked multiple times if I spoken to the pharmacist and if I could use the medication. After explaining the situation multiple times and getting transferred to multiple people it seemed everything was worked out for UPS to pick the medication up at my house, get a refund, and go pick up my medication at my local pharmacy. By the time my local pharmacy closed at 5:30 PM Friday January 13th, 2017 there still wasn't an override in place for them to be able to bill it even though I had called back yet again at 4:30 PM and spent another 15 minutes on the phone. I decided to wait it out since my last dose of this medication was Saturday morning and if I was not able to get the final dose out of my current vial I would go and get it regardless of whether it could be billed to Blue Cross Blue Shield. Somehow, I got very lucky and there was enough overfill in the vial of medication I had on hand that allowed me to get 3 extra doses out of it to complete my course of medication.

In regards to the return of the medication and the refund, that situation still has not been resolved as I write this. I was instructed that the package had been flagged for pickup and I was to leave the package outside starting Monday January 16th and UPS would attempt 3 consecutive pickups. The package was still there Monday evening and Tuesday morning. I figured UPS was just busy but then when I got home from work Tuesday evening I had a package that had been delivered from UPS sitting right next to it. This was after Prime Therapeutic's normal business hours so I called the next morning as we were driving to our appointments to let them know that the package had not been picked up and no refund had been issued. After getting transferred multiple times again, I spoke to someone who told me that could see in the notes that it was supposed to be flagged for pickup but it wasn't actually ever flagged.

The lady told me that she had it flagged and when we returned Thursday evening from our appointments the package was finally gone. It has been two months since happened to me and I still haven't received my refund of $629.05. I have called multiple times to try and get this issue resolved. I have continued to receive the run around and keep getting told that it will get escalated to the team lead. I called Prime Therapeutics again on March 13th to attempt to get the issue resolved. After being told the same thing again that it would be escalated to the team lead I asked to speak to the team lead. After waiting on hold I was told that the team lead was not yet in for the day and they would call me later. I never did receive a phone call back from the team lead and I finally decided to submit a claim with the Better Business Bureau in hopes of receiving my refund. Interestingly enough, on the Better Business Bureau website, this pharmacy has a D+ rating. I received a call back on Tuesday from the same representative that I had talked to Monday to tell me that my claim had been approved and I would see a refund on my card in the next 2-5 business days. I am not sure if my refund was finally approved due to my Better Business Bureau claim or not but I'm happy that I hopefully have some resolution to this. I am still waiting for this credit to appear on my credit card but hopefully by the 5th business day it will be on there.

This experience could have been very detrimental to me. I was very lucky that there was enough extra medication in my vial and also that I had been proactive with my local pharmacy to make sure they had it on hand in case I needed it. If I would have missed doses of this medication, it could have potentially screwed up our whole cycle of in vitro fertilization which we had already paid thousands of dollars for out of our own pockets since I do not have any insurance benefit left for these services.

Going through infertility and IVF is a very stressful situation the way it is. This situation added to the stress immensely. They claim your chances of success are better the less stress you have and I hope that this didn't have a detrimental effect to our cycle. I hope my story conveys to you the amount of extra stress this situation put me under during this critical time in my life. I have spent over 2 hours of my time on the phone with Prime Therapeutics over this situation, and it still isn't resolved. We were able to move forward with the frozen IVF cycle and are still waiting to find out the results. I know for a fact, none of this would have happened with my local pharmacy which provides excellent and timely care. When Prime Therapeutics claims they have a pharmacist on call 24/7 it is one that calls you back at their convenience. My local pharmacy is also accessible 24/7 if need be and they help you in a timely manner and provide face to face care and service. When going through a situation like infertility and IVF having compassionate care is important and there is no way any mail order pharmacy or so called "specialty" pharmacy will provide more compassionate care than my local pharmacy.

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House Industry, Business, and Labor Committee

SB 2301 – 9:30 A.M.

03/20/2017

Chairman Representative George Keiser

Mr. Chairman and members of the committee, for the record, my name is Gary Boehler, a pharmacist consultant employed by Dakota Drug, Inc. a regional drug wholesaler based in North Dakota, and serving many independent pharmacy owners in North Dakota and surrounding states. My sole purpose in consulting is to offer assistance to these pharmacies with third party (PBM) contracting and other pharmacy operational issues encountered routinely in pharmacy. I am here today to speak in support of SB 2301.

Because specialty pharmacy is the fastest growing segment of the pharmacy market, much attention is being directed to this class of drugs, and especially so by the Pharmacy Benefit Managers (hereinafter PBMs). Specialty drugs represent a major portion of the total drug spend and in 2015 was about 12% of the total spent for prescription drugs in the United States. That figure may rise by as much as 400% by the year 2020. PBMs have and continue to take advantage of their position in the drug distribution channel and as a result patients are being disadvantaged, pharmacies are being restricted from being in specialty networks as PBMs "force" specialty patients to use their own in-house, vertically integrated pharmacies. SB 2301 seeks to remedy many of these egregious activities by the PBM industry.

SB 2301 will provide a much higher level of safety to patients requiring specialty drugs. A local pharmacist will provide far more oversight with these patients than some central mail order facility 1,200 miles away, and the patients can feel comfort in knowing his/her medications will be there on time. For that reason I support SB 2301.

SB 2301 prevents PBMs from deeming generic medications or other medications that have been routinely

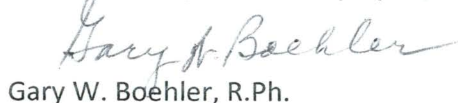
dispensed for years by retail, hospital, or nursing home pharmacies as specialty medications and thus preventing a local pharmacy from dispensing these medications. These current restrictions amount to little more than a restraint of trade. ***See Exhibit 1 as an attachment which shows drugs now being classified as specialty, yet have been in the marketplace for as many as 63 years.*** For that reason I support SB 2301.

SB2301 provides a degree of pricing transparency by requiring PBMs to disclose to an employer when and if a PBM engages in spread pricing, i.e. billing the plan sponsor more than is paid to the pharmacy. ***Exhibit 2 shows how a PBM owned pharmacy can and does engage in spread pricing. Note in this example that having a specialty medication filled through the PBM cost the patient's drug plan $105 more than going through the local pharmacy.*** For that reason I support SB 2301.

SB 2301 prevents a PBM from implementing credentialing standards which are more stringent and/or inconsistent with current federal and/or state laws. Pharmacists are already credentialed in providing many vaccinations, are trained in medication therapy management (MTM) to be able to provide one-on-one consultation for patients on specialty medications. PBM owned specialty pharmacies do NOT provide face to face consultation, not even video conferencing as telepharmacy has been using routinely in North Dakota for more than 10-12 years. For these reasons I fully support SB 2301.

SB 2301 improves patient access to these specialty drugs and preempts any attempts for PBM owned mandatory specialty mail order. For that reason I support SB 2301.

Thank you Mr. Chairman and committee members for allowing me to present this testimony on behalf of North Dakota patients, employers, and local community pharmacies.



Gary W. Boehler, R.Ph.

MANDATORY SPECIALTY DRUGS JAN. 2017

	A	B	C	D	E	F	G	H	I	J
1	Generic Name	Brand Name	Eff. Date	Tier Prior	Tier After	Year of	Class of	Avg. Cost	AWP of	Variance
2				to 1-1-17	1/1/2017	Introduction	Drug	Today	Drug	between Cost/AWP
3	Linzeloid Tablet	Daptomycin Tablet	1/1/2017	1	Specialty	2003	Antibiotic			
4	Linzeloid Oral Solution	Daptomycin Solution	1/1/2017	1	Specialty	2003	Antibiotic	$ 349.32	$ 535.54	153.3%
5	Valganciclovir Tablet	Valgan, Valstead	1/1/2017	1	Specialty	1995	Antiviral			
6	Valganciclovir Oral Solution	Valgan, Valstead	1/1/2017	1	Specialty	1995	Antiviral	$ 775.92	$ 1,000.33	128.9%
7	Voriconazole Tablet	Vfend Tablet	1/1/2017	1	Specialty	2002	Antifungal			
8	Voriconazole Oral Solution	Vfend Oral Solution	1/1/2017	1	Specialty	2002	Antifungal	$ 149.19	$ 179.03	120.0%
9	Vancomycin Capsule	Vancocin Capsule	1/1/2017	1	Specialty	1954	Antibiotic	$ 1,431.30	$ 1,717.56	120.0%
10										
11										
12										
13	1. All of these drugs have been around for a minimum of 14 years.									
14										
15	2. Had there been inherently bad side effects, serious drug interactions, or other untoward reactions, the Food & Drug Administration would have pulled them from the market.									
16										
17	3. Moving these drugs from generic tier 1 status to specialty status will raise the cost of these nine examples many times for plan sponsors and patients.									
18										
19	4. These are yet more examples of how the PBM industry schemes not to save money but rather to find ways to enrich its own pocketbooks.									
20										
21	5. This becomes yet another example of how PBM owned specialty pharmacies are shifting business to their own pharmacies vs. the community pharmacy provider.									
22										
23	6. The local pharmacist, who knows his patients and all of their other medications, is the one who should be directly involved in patient care and not a central fill pharmacy									
24	intent on filling as many prescriptions in a given amount of time with virtually NO direct patient interactions. The PBM model is not the one to embrace.									
25										
26	7. These examples above are from only one PBM. The other PBMs are doing it as well. In so doing, healthcare for our patients in our communities is being severely compromised.									
27										
28	**8. Of great significance here is although generic drugs, they are expensive. This gives the PBM the opportunity to engage in spread pricing by paying the pharmacy less**									
29	**than what is being charged to the plan sponsor. Secondarily, because they are now classified as specialty, the PBM will likely refuse to let a local pharmacy provider even**									
30	**fill the prescription by telling the plan sponsor these prescriptions are now filled at their own specialty pharmacies ("slamming").**									

P3

Exhibit 1

Gary Boehler

...n:	>
...nt:	Monday, October 17, 2016 4:20 PM
To:	Gary Boehler
Subject:	Speciality Item

1. PBM Involved

2. Name of Drug
   Forteo 600MCG/2.4ML Pen

3. Your cost to acquire the drug
   $2,435.66

4. What your employee's copay would have been filled at your pharmacy
   $0- met deductible

5. The amount your pharmacy would have been reimbursed from the PBM
   $2510.00

6. The copay your employee paid through the PBM specialty pharmacy
   $0

7. What the specialty pharmacy was paid
   $2,615.00

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Exhibit 2

Mar 20, 2017

SB 2301

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MANOR · ESTATES · THERAPEUTIC SERVICES

Members of the Industry, Business & Labor Committee:

I'm writing to voice my strong support of 2 pieces of legislation currently being reviewed by your committee, and to ask for your YES vote on both. Those pieces of legislation are SB 2301 and SB 2258.

I serve as the Administrator of a skilled nursing home/assisted living facility. In total, we provide care for 80 senior residents. In order to do so, I employ approximately 100 staff members, making our facility the 3 largest employer of our community.

I have learned of several areas of concern relating to the pharmaceutical industry. Areas of concern that if not rectified will have negative impacts on many people, including my residents and staff – which ultimately will then impact our community.

The specific areas that are of most concern relate to the definition of and requirements for dispensation of "specialty medication". As currently defined or interpreted; duly licensed, private pharmacists are prevented from dispensing these drugs, or are subject to meet unrealistic criteria to gain approval for doing so. Short of gaining this accreditation, the medications are required to be dispensed elsewhere – most often from other, in-network, pharmacies. In-network pharmacies are typically overseen by Pharmacy Benefits Managers (PBM). The very group that aided in establishing the criteria to begin with.

Herein lies the most egregious and troubling area of concern. The PBMs or their affiliates, who helped establish the "specialty medication" dispensing requirements and thus have a clear bias, are capitalizing on their status as the sole dispensing group by generating added fees. Fees either added to the cost of the prescription or attached to the dispensing pharmacy. Those fees far too often are excessive. Further concern stems from the fact this is frequently unknown to the general public due to the lack of even the most minimal degree of transparency from the PBMs. The lack of transparency prevents most patients from seeing the vast disparity in pricing that is at work through the use of PBMs/third party providers.

The result of these issues is unnecessary added steps in obtaining certain medications, often indirect and impersonal patient service, and far more costly medication than would otherwise be priced. All of which provide no enhancement or benefit to the patient, the local non-network pharmacy or the payer source.

I ask that you support SB 2301 and SB 2258 and due so as a means to provide clearer, more transparent and enhanced patient care related to "specialty medications" while entrusting local, licensed pharmacies to perform the task with which they are more than qualified to do.

Thank you for your consideration.

Sincerely,

Mitchell Page
Administrator

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11

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

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

Testimony: 2017 SB 2301

House Industry, Business and Labor Committee

Representative George Keiser, Chairman

March 20, 2017

Good morning Chairman Keiser and Members of the House Industry, Business and Labor Committee. I am Jerry E. Jurena, President of the North Dakota Hospital Association. I am here to testify regarding 2017 Engrossed Senate Bill 2301 and ask that you give it a **Do Pass** recommendation.

This bill would establish criteria regarding specialty drugs and specialty pharmacies. SB 2301 provides that a pharmacy benefits manager (PBM) or third-party payer may not require pharmacy accreditation standards or recertification requirements to participate in a network which are inconsistent with, more stringent than, or in addition to the federal and state requirements for licensure as a pharmacy in this state. The issues sought to be addressed by SB 2301 arise because there is no single agreed-upon definition of what classifies a drug as a "specialty" drug in the commercial health insurance market. Specialty drugs are generally subject to higher cost-sharing, as well as special handling requirements (i.e., refrigeration). There is also no agreed upon definition of what constitutes a "specialty pharmacy".

The cost of specialty drugs is a valid concern but we agree with the intent of the bill to introduce some common sense limits on what may be designated by a PBM or third-party payer as a specialty drug or a specialty pharmacy. Many large PBMs also own specialty mail order pharmacies, and therefore generate direct revenue from filling patient prescriptions so it is important to understand the methodology behind a PBM's classification of a product as a specialty drug. This relationship between a PBM and its own mail order specialty pharmacy raises concerns that the relationship introduces conflicts of interest. Without this bill, any drug could be designated by a PBM as a specialty drug which may require patients to fill the drug

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through a mail order pharmacy, which may be owned by the PBM or third-party payer itself. What if a PBM designates insulin, for example, as a specialty drug? The patient will have to fill the prescription through a mail order pharmacy. There would be no local pharmacist who would have the patient's prescription records and the patient will wait for the medication to come through the mail. Often, these are expensive drugs which the patient cannot afford to pay for out of pocket. Patients then want to bring these medications with them when they are admitted to the hospital and have us administer the medication. We do not know how the medication was stored, whether it has been kept under the correct temperature conditions, whether it has been taken as prescribed, or possibly even how it was prescribed. This is not a safe situation for the patient.

We are also concerned that having no checks and balances on the ability of PBMs to determine what is a specialty drug or a specialty pharmacy could adversely impact hospital revenue under the 340B program if patients are not able to get their prescriptions for specialty drugs locally. The 340B program is intended to give qualified providers, such as hospitals that serve disproportionate shares of low-income, uninsured, or underinsured patients, discounts of an estimated 20% to 50% on outpatient drugs. The savings can be used to maintain and fund services and treat patients. Some PBMs and private payers, however, have started to reduce 340B drug reimbursement rates to contracted pharmacies in order to pocket part of the savings usually reimbursed to providers. Faced with losing a substantial amount of their business, these 340B pharmacies will have no choice but to accept whatever reimbursement terms are offered by the PBM or third party payer, depriving them of the savings they need to fulfill their safety net mission. We are concerned that the trend of PBMs to have the sole ability to determine what is a specialty drug and a specialty pharmacy will eviscerate the 340B program, which would have a very detrimental effect on our hospitals' ability to continue serving low-income, uninsured, and underinsured patients.

We support this bill with the amendment described above and ask that, as so amended, you give it a **Do Pass** recommendation.

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

Respectfully Submitted,
Jerry E. Jurena, President
North Dakota Hospital Association

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BOARD OF PHARMACY
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Doug Burgum, Governor

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Mark J. Hardy, PharmD, R.Ph.
Executive Director

SB 2301 – Specialty Pharmacy Services
Industry Business & Labor Committee
8:30 AM – Monday – March 20, 2017 – Peace Garden Room

Chairman Keiser, members of the House Industry Business & Labor Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here to speak to you today about Senate Bill 2301.

The Board of Pharmacy has been increasingly aware of the term "*specialty drug*" being used in the pharmaceutical market place. We license pharmacies, both in state and out-of-state, and we have noticed an increase in number of out-of-state pharmacies that involve the dispensing of "*specialty*" medications. In its inception, "*specialty drugs or medications*" were thought to be high cost items. Recently that list of "*specialty drugs or medications*" has been extended by many Third Party Payers contracts to include medications that have been in the market place for quite some time. To be fair, there are "*specialty drugs or medications*" with distribution and dispensing limited by the Food & Drug Administration because of higher consideration of patient monitoring that are required due to the extremely complex nature of taking those pharmaceutical products. Many medications included in specialty drug lists by Third Party Payers appear to be products that are available and have been dispensed by pharmacies for several years.

The Board of Pharmacy has heard from the public through complaints in which the individual is concerned about being required to obtain their medications through the mail. The patient is often concerned that these expensive medications maybe subjected to extreme temperatures in the process. Often the person wishes to obtain their medication from their local pharmacy. However, the Third-Party Payer limits the opportunity for their pharmacy to dispense that product to them. This is not typically due to the pharmacy's ability to obtain and dispense the medication, but the Third-Party Payer's preference.

Another growing trend in the market place is to require the pharmacy to submit to an accreditation process devised by the Third-Party Payer to be eligible to dispense to patients of that Third-Party Payer medications deemed "*specialty drugs or medications*".

The North Dakota State Board of Pharmacy has long adhered to the premise that our pharmacists and pharmacies are equally licensed. As long as they have met all the requirements and acquired the appropriate state and federal licenses, they should be allowed to dispense any and all pharmaceutical products set forth in that practice. We strongly believe the patient should decide the pharmacy of their choice.

In summary, the Board of Pharmacy is supportive of defining "*specialty drugs or medications*" and ensuring the patient's access to the pharmacy of their choice.

I will be happy to answer any questions you may have, and do appreciate your time.

Mar 20, 2017 SB 2301 13

March 18, 2017

I am writing today in support of SB2301 relating to Specialty Pharmacy Services.
I use Humira injections, and have BCBS ND.
I have been on this medication for about 4 and ½ yrs, and was told by BCBS about 1 and ½ yrs ago that I had to get it from Prime Specialty Mail Pharmacy.
The only benefit I see is that the Insurance Company discounts the price for it's members. (Although they do this at retail as well.)
I don't feel the specialty pharmacy was any more professional than my local pharmacist, and they are usually not very personable.
I have experienced delays in getting my medication due to weather, when using Prime Specialty, and have caught the delivery driver trying to deliver it to my neighbor's house.
What sense does it make to get meds from many states away, when the local pharmacy is less than 3 blocks away and besides, they deliver too. The real problem is the cost of these drugs. For Instance, Humira saw 3 price increases in a yearly span, a $1,200 increase in the last yearly span alone! Go figure. Ask the manufacturer of Humira that question. I can't get an answer.
I'm afraid even if this bill passes, the specialty pharmacies and the insurance companies that own them will find a way around the bill, and pass costs on the insured members.

Tim Stiner

303 1st Ave SW
Garrison, ND 58540
701-463-7362

Mar 20, 2017

SB 2301 Testimony

Good morning Mr. Chairman and members of the committee. My name is Abigail Stoddard, I am pharmacist for Prime Therapeutics. I am here this morning to respectfully oppose SB 2301.

First and foremost, SB 2301 would remove our ability to selectively create specialty pharmacy networks. Specialty pharmacy networks keep patients safe, ensure they have reliable access to medications and specially trained pharmacists, and are a key cost control tool to combat the rising costs of life saving drugs.

Specialty drugs require care coordination using personnel specifically trained in the disease states treated by the drugs. These personnel work with the patients and physicians to address side effects, drug interactions, and track the outcomes for specific patients. These standards of care are not accounted for in a typical state pharmacy license and require extra credentialing by independent third parties such as URAC. I'd like to illustrate this with specific example – Remodulin – a drug used to treat pulmonary arterial hypertension. This drug comes in a simple vial. Each dose of the drug, however, must be given to the patient along with needles, syringes, alcohol swabs, bandages, herparin flushes, sodium chloride flushes, sterile water, and an infusion pump. As you can imagine, this also requires the patient get the correct instructions on how to prepare the drug, use the pump, care for their IV lines and have a provider available 24/7 should they need help. Using a specialty pharmacy ensures our health plans that these patients receive the attention and care coordination needed to use these drugs safely and effectively.

In addition to being a complicated drug to use each vial costs approximately $3,000 and a patient may multiple vials each month. Specialty pharmacies are an important channel that can exact leverage from the drug manufacturers to lower prescription drug costs. In North Dakota Prime's specialty pharmacy network is projected to save our client's approximately half a million dollars in 2017. The $3,000 price tag I just mentioned may sound like a lot, but that is just the beginning. New specialty drugs enter the market every day, and there is no ceiling on their cost. Take the last 6 drugs approved by the FDA in 2016 – 5 of them were specialty drugs, the last of which made headlines around the country as being the not only first treatment for spinal muscular atrophy but also for its price tag of $750,000 a year. Our clients want to cover block-buster drugs like this for our members, and specialty pharmacy networks are an essential tool to drive discounts and contain costs so they are able to do so. When similar legislation was considered in Minnesota it received a fiscal note estimating the cost to the state at $7.8 million dollars over the next 2 years.

Last, sections 2 and 3 of the bill address the contracts PBMs have with their clients. North Dakota code chapter 26.1-27.01 and 26.1-27.1 already specify transparency requirements in PBM-client contracts, including our affiliation with entities providing pharmacy services. Further state interference in these agreements is not necessary. Thank you for your time.

Testimony of Pat Ward in Opposition to Engrossed SB 2301
House IBL – Monday, March 20, 2017 – 8:30 a.m.

- Good morning, Chairman Keiser and members of the House IBL Committee. My name is Patrick Ward, a Bismarck lawyer, and I am here on behalf of Express Scripts (ESI) – one of the nation's largest pharmacy benefit managers – in opposition to Engrossed SB 2301.

- I would first like to introduce to you, Andy Behm, who is one of our specialty pharmacists, and Dave Dederichs, from our government relations division. They are here to help answer any questions you may have about 2301 and 2258, or their business.

- As a pharmacy benefit manager (PBM), it is our goal to make prescription drugs ***safer and more affordable*** for our clients, as well as their beneficiaries.

- PBMs do this in a variety of ways: by negotiating discounts from brand drug manufacturers, designing retail pharmacy networks, promoting generics, operating specialty pharmacies, providing formulary management, performing drug utilization reviews, and many other things. ESI performs these services for tens of millions of Americans through our clients -- including Fortune 500 employers, health plans, labor unions and government entities of all sizes.

- **Our clients design their pharmacy benefits** to meet the unique needs of their respective workforces. We, then, as a PBM, administer that benefit. The details of how that benefit is structured, including the pharmacy network, *are determined by the plan sponsor/client.* These are sophisticated contracts negotiated by knowledgeable experts with great resources.

- We are here in total opposition to Engrossed SB 2301. Specifically, paragraphs 3, 4, and 5 of section 1, all *serve to eliminate specialty pharmacy net*works as an option for plan sponsors when designing their benefits.

- Whether clients want fewer pharmacies in their network, or whether they want a specific network of specialty pharmacies for their beneficiaries, this legislation would prohibit that freedom of contract. Narrow, or even specialty, networks can offer savings opportunities for clients and patients, as well as offer specialized care.

- Moreover, certain *federal REMS (risk evaluation and mitigation strategies) programs and even some drug manufacturer agreements* ***require*** limited distribution of specialty products – **because only a small subset of pharmacies – specialty pharmacies – are equipped to store and dispense these products**. This legislation contravenes those principles.

- Specialty drugs are used to treat rare diseases and may not be stocked at typical brick-and-mortar drug stores. Given the sophisticated handling and distribution requirements of specialty drugs, the number of facilities equipped to handle the needs of specialty patients is lower still. Of the 69,000 pharmacies in the United States, relatively few qualify as specialty pharmacies. Since not all pharmacies provide the same level of clinical care and product support to ensure that patients have access to the right medications at the right time, ***payers must differentiate which pharmacies*** *provide comprehensive specialty care versus those unable to achieve similar service levels and outcomes.*

- Unlike traditional brick-and-mortar drugstores, specialty pharmacies employ highly trained teams of pharmacists, nurses,

and clinicians (with disease state expertise) to work with doctors and patients to ensure those complex medications are administered on time, conveniently, safely and effectively.

- Specialty pharmacies provide a broad range of services that help patients with unique needs, including:
  - Providing around-the-clock access to specially trained clinicians who offer patients guidance and insight on disease states, as well as the use of specialty drugs;
  - Consulting directly with physicians to address patient side effects, adverse drug reactions, non-adherence, and other patient concerns;
  - Performing disease and drug-specific patient care management services;
  - Collecting data and tracking outcomes for specific patients;
  - Managing patient adherence and persistency of drug regimens; and,
  - Managing care for manufacturer REMS program requirements, including reporting, Phase IV trials, the dispensing of FDA trial drugs under strict protocols, and related clinical and cognitive counseling.
- I can provide some additional background information on this issue if anyone is interested, I will leave a copy with Ellen for now, of the following:
  1. Exhibit A is an article regarding anticompetitive effects of any willing provider (AWP) laws.
  2. Exhibit B discusses a CMS analysis that specialty pharmacies will save consumers $250 billion over the 10 year period

2015-2024. Specialty drugs will soon be 50% of US drug spend.

3. Exhibit C is a white paper on specialty pharmacy and why it does not translate to brick and mortar pharmacies.

4. Exhibit D, MN Fiscal Note, p. 1 of 16. **Why is there not a fiscal note on this bill? The costs associated with this can be substantial**. 2 years ago, Minnesota had a similar bill. The fiscal note in that state was substantial and the bill was defeated.

- Finally, page 1, paragraph (2), lines 19-21, is also objectionable. While not relating directly to specialty pharmacy services, this paragraph would legislatively **dictate contract terms between private market entities.** PBM clients are sophisticated purchasers that customize their pharmacy benefits, and corresponding contracts, to their needs. If a client wants this type of information included in their contract, they can simply negotiate for this information. This language would hamstring freedom of contract.

- Section 2, page 2, lines 13 and 14, unconstitutionally attempts to rewrite existing contracts and is subject to challenge.

- For all the aforementioned reasons, we urge a Do Not Pass on SB 2301. We will try to answer any questions you have.

P:\PWARD\Legislative 2017\Testimony - SB 2301.doc

Mar 20, 2017 SB 2301 16

1) Accredo specialty pharmacy provides comprehensive specialty services for rare, high cost conditions.

2) The Accredo services transcend those found in your typical corner drug store and include 24/7 access to a pharmacist, nurse, and social worker; in home nursing support; patient reimbursement assistance; and a wide range of adherence tools.

3) The Accredo pharmacy services lead to better adherence rates, fewer unscheduled physician office visits, fewer ER visits, and reduced medical costs when compared with retail pharmacies.

4) Clients (employers, health plans, etc.) determine which specialty pharmacies are in their network. They also establish the standards that a specialty pharmacy must meet.

5) Accredo employs nurses and pharmacists who are experts in the care of these rare patients. Our employees develop personal relationships with these patients and become an integral part of the health care team.

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GNDC
Greater North Dakota Chamber

Testimony of Andy Peterson
Greater North Dakota Chamber of Commerce
SB 2301
Industry, Business, and Labor
Honorable George Keiser - Chair
March 20, 2017

My name is Andy Peterson and I am representing the Greater North Dakota Chamber. The GNDC works on behalf of all our members to support building a strong, vibrant business climate in North Dakota. GNDC stands today in opposition of SB 2301.

The GNDC recognizes the importance of having a business environment which allows businesses and industries to find the most effective and efficient way to perform services and produce goods. SB 2301 creates limitations for a business to do just that, while also forcing a business to disclose negotiated terms and pricing. Businesses should be allowed to maintain confidentiality in the terms they have negotiated between private parties.

We believe it not the state's role to limit businesses opportunities to find efficiencies which help to provide increased benefits to the consumer by keeping costs low. We, at the GNDC, have always believed the state should not be in the role of picking winners or losers in certain industry or business segments. Each business should be able to compete in the marketplace without having conditions which limits its ability to compete, whether through being required to disclose pricing or being told it cannot use the efficiencies it has created within its business model.

Chairman, members of the committee GNDC urges a Do Not Pass on SB 2301 and I would stand for any questions you may have.

Champions for Business

PO Box 2639
Bismarck, ND 58502
P: 701-222-0929
F: 701-222-1611

www.ndchamber.com

18

SB2301
Testimony
March 20, 2017

ND

Good Morning Chairman Keiser and Committee Members. My name is Mike Potts. I am the Vice President of Health Innovation and Practice Transformation at Blue Cross Blue Shield of North Dakota (BCBSND).

I am here to testify in opposition to Senate Bill 2301.

Blue Cross Blue Shield of North Dakota's goal is to be a good partner with the North Dakota pharmacy community and to also ensure that our health insurance customers receive the best value in specialty pharmacy services. I do not believe this bill, if passed, is in the long-term best interests of Blue Cross Blue Shield of North Dakota members.

The Willis Towers Watson 2016 Employer Best Practices in Healthcare study reported that 87 percent of employer respondents indicated that "Cost pressures - notably for specialty drugs - continue to drive employers to change their benefit programs."

In 2016, less than one percent of Blue Cross Blue Shield of North Dakota's members were on a specialty medication, but the specialty costs accounted for 44 percent of all pharmacy spending. Specialty pharmacy costs in 2016 increased by 16 percent over 2015 on a per member basis and are expected to continue rising as new drugs enter the market. In 2016, BCBCND spent as much for pharmacy as inpatient hospital services.

The average cost of specialty drug claims paid by Blue Cross Blue Shield of North Dakota exceeds $5,000. Spinraza, a drug for treating spinal muscular atrophy, was recently approved by the FDA, with first-year treatment costs exceeding $750,000 and annual expected costs of $375,000 thereafter.

Specialty pharmacy medications are becoming increasingly important and are the fastest growing facet of our health care system. There is no universal definition of a "specialty drug," but the pharmacy industry-accepted classification generally includes criteria related to disease complexity, patient education and monitoring, special storage or handling and cost thresholds. Specialty drugs are commonly defined for treating Hepatitis C, Multiple Sclerosis, Cancer, Autoimmune Disorders and others.

Large, self-funded employers, including many Blue Cross Blue Shield of North Dakota customers, have implemented aggressive strategies to manage specialty costs, including specialty benefit tiering, utilization management programs, specialty mail order and limited network solutions.

As Specialty Pharmacy has grown, stakeholders and pharmacy professional organizations have defined minimum standards of care delivery for specialty pharmacy. Several accreditation agencies now recognize and accredit specialty pharmacy practice, including URAC (formerly Utilization Review Advisory Commission), Accreditation Commission for HealthCare (ACHC) and The Center for Pharmacy Practice Accreditation (CPPA). The CPPA, formed by a number of leading pharmacy organizations has focused on providing accreditation for community pharmacies so they can compete with institutional or centralized, mail-specialty pharmacies.

Employers, consultants, pharmacy benefits managers and other purchasers need assurance that high-cost specialty medications are used safely and appropriately to optimize outcomes. Specialty pharmacy accreditation helps ensure these goals are met.

Blue Cross Blue Shield of North Dakota has been a strong partner for North Dakota community pharmacies. Recognizing our customers' need to know specialty medications are priced competitively, used correctly and the value of local access, BCBSND began efforts in 2015 to establish a specialty network that included local community pharmacies. To participate in the network, pharmacies were asked to seek accreditation.

Throughout the process, BCBSND worked with the North Dakota Pharmacist Association and local pharmacies. The specialty network went live in March of 2016 and is comprised of approximately 190 pharmacies. The vast majority of network pharmacies are community pharmacies, including 47 North Dakota locations that offer local high quality and competitively priced services to North Dakotans.

Passage of SB2301 will reverse this progress made in the past year and I urge a Do Not Pass.

Thank you for your time. I will now take any questions.

Mike Potts
Vice President of Health Innovation and Practice Transformation
Blue Cross Blue Shield of North Dakota

Fargo-Moorhead Home Builders
HEALTH PLAN & TRUST

1802 32nd Ave. S.
Fargo, ND 58103

(701) 232-5846
Fax (701) 280-1108

2017
PLAN MANAGEMENT
COMMITTEE

CHAIR
Jason Eid

SECRETARY
Terry Welle

TRUSTEES
Toby Christensen
Terry Cullen
Jeff Slaby
Tom Spaeth
Matt Warren

NON-VOTING TRUSTEE
Tyrone Leslie

ADMINISTRATOR
Bryce Johnson

March 17, 2017

North Dakota Legislature
House Industry, Business and Labor Committee
Chairman George Keiser
600 E Boulevard Ave
Bismarck, ND 58505

Dear Chairman Keiser and Committee Members:

Our health plan, which is a multiple-employer welfare arrangement, serves thousands of North Dakota residents and families. We strive to keep comprehensive services available at an affordable price to them. To that end, we rely on our health plan administrator, Blue Cross Blue Shield North Dakota, for solutions toward cost-effective health care delivery, management and finance.

Please oppose SB 2301 which prevents BCBSND from operating its specialty network and key plan design features important to maintain the coverage we provide: this bill will result in higher costs for specialty drugs, which is one of the fastest growing components of health care spending, and a major issue for the families and individuals we serve.

BCBSND has found a North Dakota way to meet our health plan participants' needs. By applying "Specialty Pharmacy Credentialing" in pharmacies dispensing to those with complex and costly conditions, specialty drug management helps bring their costs down. It eases the burden on North Dakota families and residents.

BCBSND employs the basic industry pillars to specialty management:

1. identify the targeted "specialty drugs,"
2. employ care management to those requiring specialty drugs, and
3. use benefit design to drive adoption of specialty management.

This is a strategy to improve the quality of care the specialty patient receives and decreases costs for all. We urge you to continue allowing BCBSND to manage specialty drugs with the approaches they've developed to provide high-quality broad access, which meets the needs of our health plan participants.

Sincerely,

Jason Eid
Chair

Bryce Johnson
Plan Administrator

p3

3/20/2017

Dear Representative:

To remain a successful North Dakota Company, meeting the needs of our employees and their families means providing a comprehensive health plan at an affordable price. We rely on our health plan, Blue Cross Blue Shield North Dakota, for solutions towards cost-effective health care delivery, management and finance.

Among the fastest growing components of health care spending is the specialty drug category. We have experienced growth in spending due to more therapies and their rising costs. When it comes to specialty drugs; efforts directed at a few, benefit all. BCBSND has found a North Dakota way to meet our needs as a client. By employing applying "Specialty Pharmacy Credentialing" in pharmacies dispensing to those with complex and costly conditions, specialty drug management brings values to all members of the plan. BCBSND employs the basic industry pillars to specialty management: 1.) identify the targeted "specialty drugs", 2.) employ care management to those requiring specialty, and 3.) use benefit design to drive adoption of specialty management.

This is a strategy to improve the quality of care the specialty patient receives and decreases costs for all. We urge you to continue allowing BCBSND to manage specialty drugs with the approaches they've developed to provide high-quality broad access, which meets the needs of our members. Please consider opposing SB 2301 which prevents BCBSND from operating its specialty network and key plan design features important to maintain the coverage we provide our employees and their families.

Sincerely,

Melissa Lunak

Melissa Lunak, Director of HR

p4

P 701.237.6000 4650 26 AVE SOUTH SUITE E FARGO, ND 58104
F 701.237.9082 brandtholdings.com

March 20, 2017

Dear Representative:

To remain a successful North Dakota Company, meeting the needs of our employees and their families means providing a comprehensive health plan at an affordable price. We rely on our health plan, Blue Cross Blue Shield North Dakota, for solutions towards cost-effective health care delivery, management and finance.

Among the fastest growing components of health care spending is the specialty drug category. We have experienced growth in spending due to more therapies and their rising costs. When it comes to specialty drugs; efforts directed at a few, benefit all. BCBSND has found a North Dakota way to meet our needs as a client. By employing applying "Specialty Pharmacy Credentialing" in pharmacies dispensing to those with complex and costly conditions, specialty drug management brings values to all members of the plan. BCBSND employs the basic industry pillars to specialty management: 1.) identify the targeted "specialty drugs", 2.) employ care management to those requiring specialty, and 3.) use benefit design to drive adoption of specialty management.

This is a strategy to improve the quality of care the specialty patient receives and decreases costs for all. We urge you to continue allowing BCBSND to manage specialty drugs with the approaches they've developed to provide high-quality broad access, which meets the needs of our members. Please consider opposing SB 2301 which prevents BCBSND from operating its specialty network and key plan design features important to maintain the coverage we provide our employees and their families.

Sincerely,

Michael Vannett
Treasurer/Secretary

P5

PO Box 5006
Minot, ND 58702-5006
(701) 857-4756
(701) 857-4751 Fax
hr@minotnd.org

City of Minot
Human Resources

3/20/2017

Dear Representative:

To remain a successful North Dakota Company, meeting the needs of our employees and their families means providing a comprehensive health plan at an affordable price. We rely on our health plan, Blue Cross Blue Shield North Dakota, for solutions towards cost-effective health care delivery, management and finance.

Among the fastest growing components of health care spending is the specialty drug category. We have experienced growth in spending due to more therapies and their rising costs. When it comes to specialty drugs; efforts directed at a few, benefit all. BCBSND has found a North Dakota way to meet our needs as a client. By employing applying "Specialty Pharmacy Credentialing" in pharmacies dispensing to those with complex and costly conditions, specialty drug management brings values to all members of the plan. BCBSND employs the basic industry pillars to specialty management: 1.) identify the targeted "specialty drugs", 2.) employ care management to those requiring specialty, and 3.) use benefit design to drive adoption of specialty management.

This is a strategy to improve the quality of care the specialty patient receives and decreases costs for all. We urge you to continue allowing BCBSND to manage specialty drugs with the approaches they've developed to provide high-quality broad access, which meets the needs of our members. Please consider opposing SB 2301 which prevents BCBSND from operating its specialty network and key plan design features important to maintain the coverage we provide our employees and their families.

Sincerely,

Lisa R Jundt

Lisa R. Jundt, MBA
Human Resource Director/Authorized Group Plan Agent
City of Minot

p6

ND REC
BENEFIT TRUST

3/20/2017

Dear Representative:

Please consider opposing SB 2301. The bill provides that any pharmacy licensed in North Dakota would be authorized to dispense any and all drugs, and a pharmacy benefits manager or third-party payor would not be able to require pharmacy accreditation standards that are more stringent than current state law. The ND REC Benefit Trust strives to provide North Dakota's rural electric cooperatives a high quality and comprehensive health plan, at an affordable price, for the 1,111 employees insured and their families. In part, we rely on our health plan Blue Cross Blue Shield North Dakota (BCBSND) for solutions toward cost-effective health care delivery, management and finance. Passage of SB 2301 would diminish our efforts to contain costs and compromise the standard of care when dispensing specialty drugs.

Pharmaceuticals are one of the fastest-growing components of health care spending. However, BCBSND has found a way to curb costs by applying "Specialty Pharmacy Credentialing" in pharmacies dispensing specialty drugs. Pharmacies credentialing standards include cost limits on the dispensing of specialty drugs.

In addition, accredited pharmacies employ BCBSND specialty drug management that brings value to all members of the plan. BCBSND applies these basic industry pillars to specialty drug management: 1) identify the targeted "specialty drugs," 2) employ care management to those requiring specialty drugs, and 3) use benefit design to drive adoption of specialty management. Using these strategies improves the quality of care the specialty patient receives and decreases costs for all.

We urge you to oppose SB 2301 so BCBSND can continue to manage specialty drugs with the approaches they've developed, which provide high-quality, broad access that meets the needs of our members. If passed, the bill will prevent BCBSND from operating its specialty network and key plan design features that are important to maintaining the coverage we provide our ND REC employees and their families.

Sincerely,

Josh Kramer
ND REC Benefit Trust Chair

p7

3201 NYGREN DR. N.W. | P.O. BOX 727 | MANDAN, ND 58554 | 701-663-6501 | F 701-663-3745

SCHEELS

Corporate Office • 4550 15th Avenue South • Fargo, ND 58103 • (701) 232.3665 • fax (701) 232.3735

3/15/2017

Dear Representative:

To remain a successful North Dakota Company, meeting the needs of our employees and their families means providing a comprehensive health plan at an affordable price. We rely on our health plan, Blue Cross Blue Shield North Dakota, for solutions towards cost-effective health care delivery, management and finance.

Among the fastest growing components of health care spending is the specialty drug category. We have experienced growth in spending due to more therapies and their rising costs. When it comes to specialty drugs; efforts directed at a few, benefit all. BCBSND has found a North Dakota way to meet our needs as a client. By employing applying "Specialty Pharmacy Credentialing" in pharmacies dispensing to those with complex and costly conditions, specialty drug management brings values to all members of the plan. BCBSND employs the basic industry pillars to specialty management: 1.) identify the targeted "specialty drugs", 2.) employ care management to those requiring specialty, and 3.) use benefit design to drive adoption of specialty management.

This is a strategy to improve the quality of care the specialty patient receives and decreases costs for all. We urge you to continue allowing BCBSND to manage specialty drugs with the approaches they've developed to provide high-quality broad access, which meets the needs of our members. Please consider opposing SB 2301 which prevents BCBSND from operating its specialty network and key plan design features important to maintain the coverage we provide our employees and their families.

Sincerely,

Michelle Killoran, CFO
Scheels Corporate Office

p8

3/20/2017

Dear Representative:

To remain a successful North Dakota Company, meeting the needs of our employees and their families means providing a comprehensive health plan at an affordable price. We rely on our health plan, Blue Cross Blue Shield North Dakota, for solutions towards cost-effective health care delivery, management and finance.

Among the fastest growing components of health care spending is the specialty drug category. We have experienced growth in spending due to more therapies and their rising costs. When it comes to specialty drugs; efforts directed at a few, benefit all. BCBSND has found a North Dakota way to meet our needs as a client. By employing applying "Specialty Pharmacy Credentialing" in pharmacies dispensing to those with complex and costly conditions, specialty drug management brings values to all members of the plan. BCBSND employs the basic industry pillars to specialty management: 1.) identify the targeted "specialty drugs", 2.) employ care management to those requiring specialty, and 3.) use benefit design to drive adoption of specialty management.

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Sincerely,

Everett Iron Eyes, Jr.
General Manager

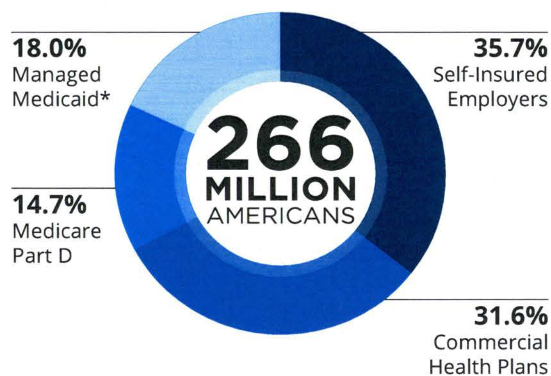
p9

ABOUT PCMA

The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans who have health coverage from a variety of sponsors. PCMA continues to lead the effort in promoting PBMs and the proven tools they utilize, which are recognized by consumers, employers, policymakers, and others as key drivers in lowering prescription drug costs, increasing access, and improving outcomes.

PBMs serve consumers across plan types

Americans With Drug Benefits Managed by PBMs, by Type of Coverage



* Excludes "Medicare/Medicaid Dual Eligibles" where drugs are covered by Medicare Part D

How PBMs reduce drug costs

- Encouraging the use of generics and affordable brand medications
- Reducing waste and increasing adherence to improve health outcomes
- Offering home delivery of medications and creating networks of affordable and high quality pharmacies
- Negotiating rebates from drug manufacturers and discounts from drugstores
- Managing high-cost specialty medications

PBMs promote pharmacy access

PBMs work with health plans, employers, and government programs to ensure that their members and employees have access to necessary medications through a variety of phamacies, including retail, community, mail order, and specialty pharmacies.

PBM savings

PBMs are projected to save employers, unions, government programs, and consumers $654 billion — up to 30 percent — on drug benefit costs over the next decade, according to research from Visante.

$654 BILLION SAVINGS

PCMA MEMBERS

p1

Source: Visante, estimates prepared for PCMA. (2016).

© Pharmaceutical Care Management Association

PBM BEST PRACTICES

PBMs work to deliver the lowest net cost of drugs for their clients and improve patient health outcomes.

PBMs offer their clients programs that facilitate timely patient appeals to help ensure appropriate medication use.

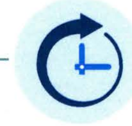
PBMs provide clients with audit rights in their contracts.

PBMs perform drug utilization reviews to help reduce drug-drug interactions, increase patient safety, and improve appropriate use.

PBM clients are entitled to negotiate all client contractual terms, including rebate arrangements ranging from 100% pass-through to shared savings.

PBMs offer network options that include high quality, credentialed pharmacies.

PBMs provide clients with programs to protect against drug manufacturer price inflation.



PBMs provide patients 24-7 access to pharmacists or other clinicians.

PBMs utilize independent clinical experts and specialists to develop formularies and clinical programs to help ensure patients have access to clinically appropriate treatments.

PBMs guarantee financial terms and service levels to maximize overall contract value.

p2

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PBMs ARE TRUSTED BUSINESS PARTNERS FOR HEALTHCARE PAYERS

Pharmacy Benefit Managers (PBMs) Play a More Critical Role Than Ever for Payers (Plan Sponsors) and Patients in Keeping the Cost of Healthcare Affordable

Ever-growing

3.2+ million U.S. businesses offer health and prescription benefits to **156 million employees and their families.** Government healthcare programs, such as Medicare, Medicaid, and the Veterans Administration (VA), also provide prescription benefits to more than **112 million beneficiaries** across the country.

Highly competitive

There are more than **80 PBMs** in the U.S. that offer a wide range of drug plan options to payers, allowing these plan sponsors to receive services that meet their unique program needs. This includes **100% pass-through, transparent rebate arrangements.**

Expert counsel

Over 90% of plan sponsors work with expert healthcare and pharmacy benefit consultants to help provide guidance when making pharmacy benefit decisions and negotiating their PBM contracts.

Important ways PBMs excel at service

Transparency to clients

PBMs' transparent contracts continue to drive high levels of customer satisfaction. They clearly define terms for financial calculations, helping clients understand what they are buying.

✔ **Key fact:** PBM contracts include disclosures and pass-through offerings to ensure transparent pricing at the level the plan sponsor chooses.

Price protection offerings

To help control skyrocketing drug prices by pharmaceutical companies, many PBMs offer their clients price protection services as a part of their contract — ultimately delivering high dollar value to plan sponsors.

✔ **Key fact:** Pharmaceutical industry monopolies cause rampant price increases and high cost trends. In 2015, average brand name drug prices rose over 16%, with more than one-third of those seeing a 20% increase.

Allow clients the right to audit

Audits help ensure the integrity of the PBM contract, and verify that the plan sponsor and its members are receiving the full benefit of the contract.

✔ **Key fact:** Auditors are able to follow claims through the system so appropriate pricing and crediting of rebates can be confirmed. For example, clients can ask to review the numbers behind network pharmacy discounts and the amount of rebates being passed back to them.

Flexible formulary and benefit designs

PBMs support their clients' efforts to balance cost-sharing with strategies that drive value and ensure access to the right medication at the right price.

✔ **Key fact:** Formulary management ranked highest in satisfaction among services offered by many PBMs.

p3

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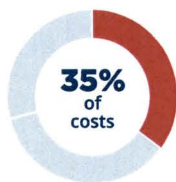
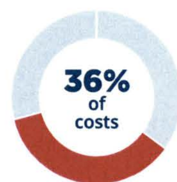
PBMs SAVE ON PRESCRIPTION COSTS FOR PATIENTS AND PLANS

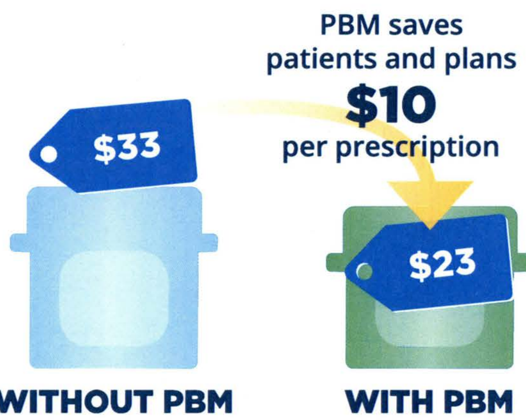
GENERICS

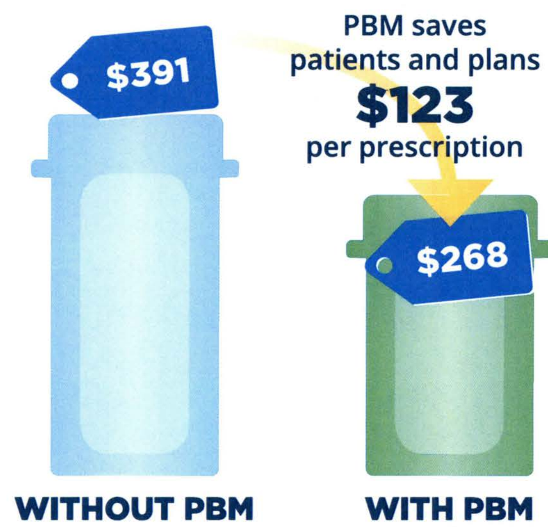


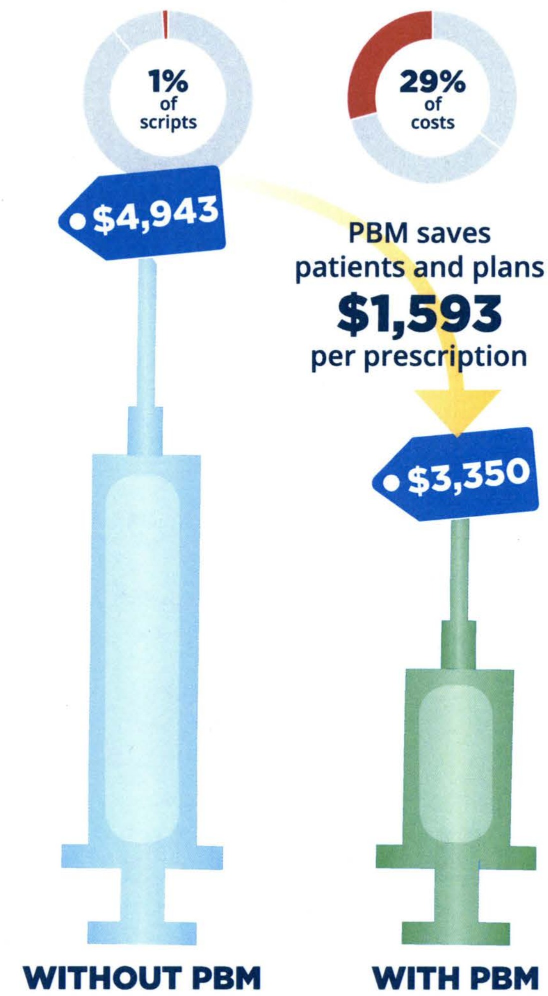
BRANDS



SPECIALTY







Note: Market share estimates based on net costs. PBM = Pharmcay Benefit Manager.
Source: PCMA based on Visante analysis. (2017).

PCMA

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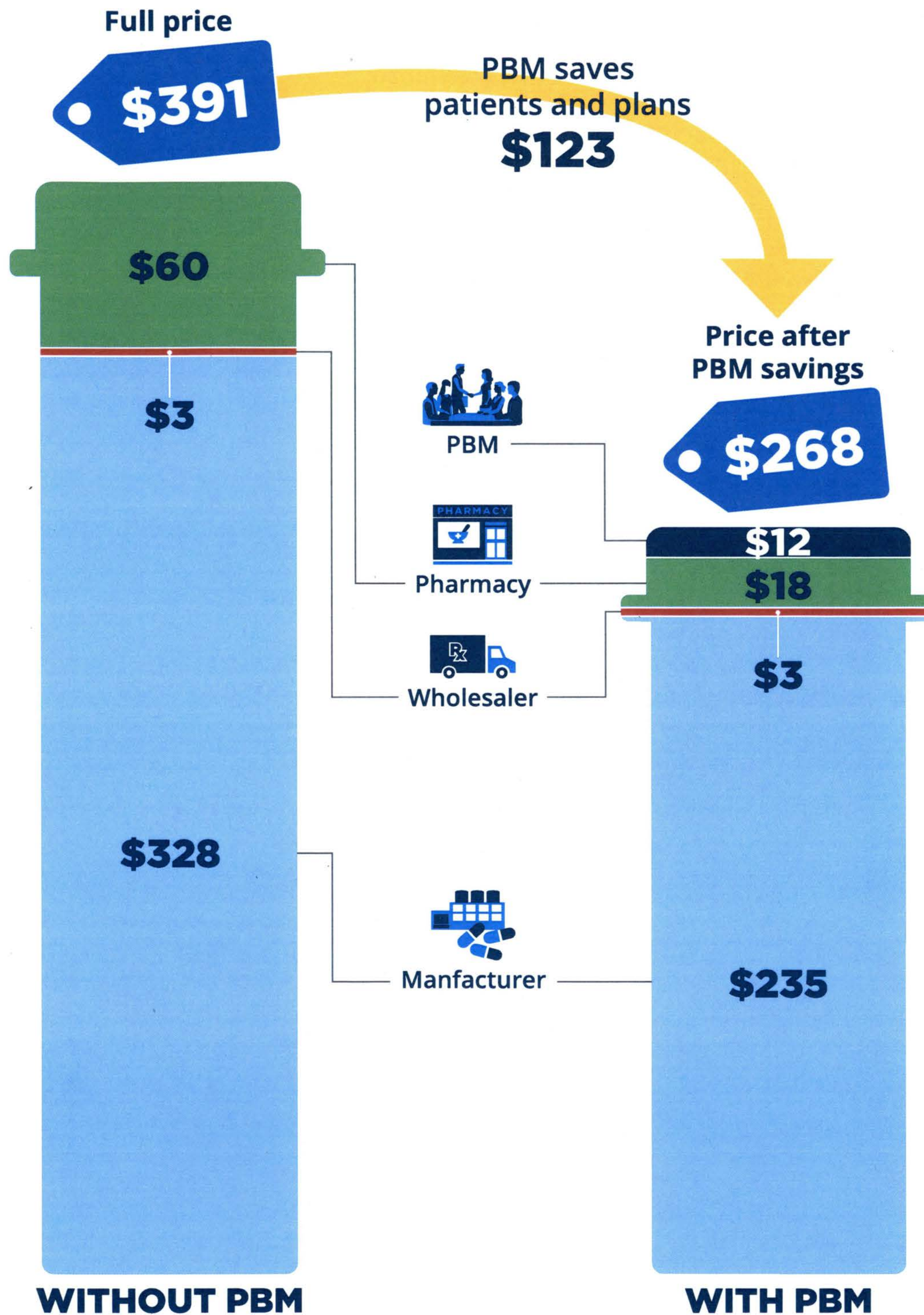
www.pcmanet.org

PBMs SAVE PATIENTS AND PLANS $123 PER PRESCRIPTION*



p5

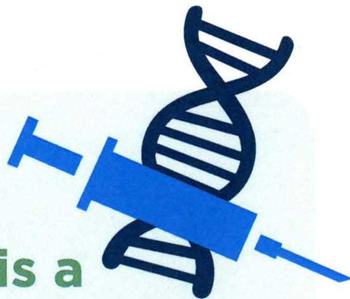
*Comparison based on non-specialty brands. PBM = Pharmacy Benefit Manager.
Source: PCMA based on Visante analysis. (2017).

PCMA

© Pharmaceutical Care Management Association

www.pcmanet.org

PBMs' MANAGEMENT OF SPECIALTY DRUGS



What is a specialty drug?

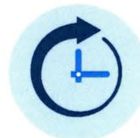
A specialty drug possesses any number of these common attributes:[1]

- Prescribed for a person with a complex or chronic medical condition
- Treats rare or orphan diseases
- Requires advanced patient education, adherence, and support
- Is oral, injectable, inhalable, or infusible
- Has a high monthly cost
- Has unique storage or shipment requirements
- Is not stocked at a majority of retail pharmacies

What are specialty pharmacies?

- Payer-aligned specialty pharmacies have the **technology and clinical expertise** to enhance the safety, quality, and affordability of care for patients receiving specialty medications
- Pharmacists and clinicians at specialty pharmacies offer support to patients with complex medical conditions, such as:
  - Blood disorders
  - Cancer
  - Crohn's disease
  - HIV/AIDS
  - Infertility
  - Multiple sclerosis
  - Rheumatoid arthritis
  - Among others

Specialty pharmacies play an important role in patient care. They provide:



24/7 access to specially trained pharmacists and clinicians

Physician consultations to address patient side effects, adverse reactions, and non-adherence

Patient care management services to ensure patient safety

Data analytics that drive better patient outcomes

1 sPCMA, *The Managment of Specialty Drugs*. (2016).

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Specialty drug benefit design and management

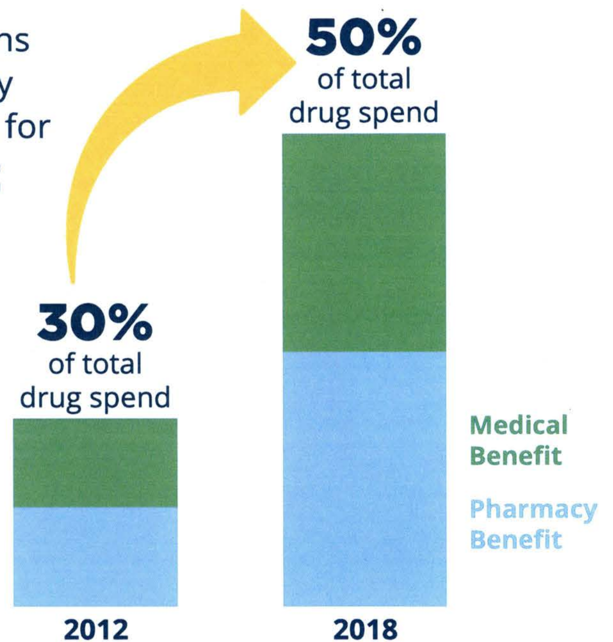
PBMs have developed key strategies to maintain access to high-quality care while ensuring that money spent on specialty drugs is not wasted:

- Negotiating rebates from drug manufacturers
- Creating high-quality preferred networks
- Offering more affordable pharmacy channels, such as home delivery and specialty pharmacies
- Optimizing appropriate sites of care
- Encouraging use of the highest-value drug options
- Reducing waste and improving adherence

Effective management is needed

In 2020, **9 of the 10** best-selling drugs by revenue will be specialty drugs, compared with 3 out of 10 in 2010, and 7 out of 10 in 2014[2]

By 2018, projections show that specialty drugs will account for **50 percent** of all drug costs[3]



Compared to traditional retail drugstores, specialty pharmacies offer deeper discounts and enhanced services to employers and consumers. Specialty pharmacies will **save an estimated $250 billion** over the 10-year period 2016–2025.[4]

2 Drug Channels, *Pharma's Bright Future: Meet the Top 10 Drugs of 2020*. (July 28, 2015).
3 CVS Health, *Insights: Specialty Pipeline: Blockbusters on the Horizon*. (2016).
4 Visanate, *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers*. (February 2016).

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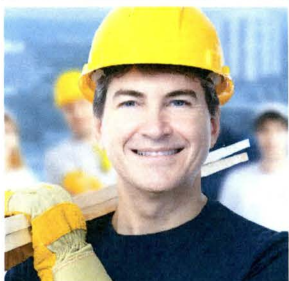
PBM SOLUTIONS FOR PATIENTS AND PAYERS

Reducing Prescription Drug Costs

Designing Solutions for Employers, Unions, and Government Programs



Delivering High Patient Satisfaction and Improved Outcomes

Improving Patient Access, Safety, and Convenience

Preventing Fraud, Waste, and Abuse

PCMA

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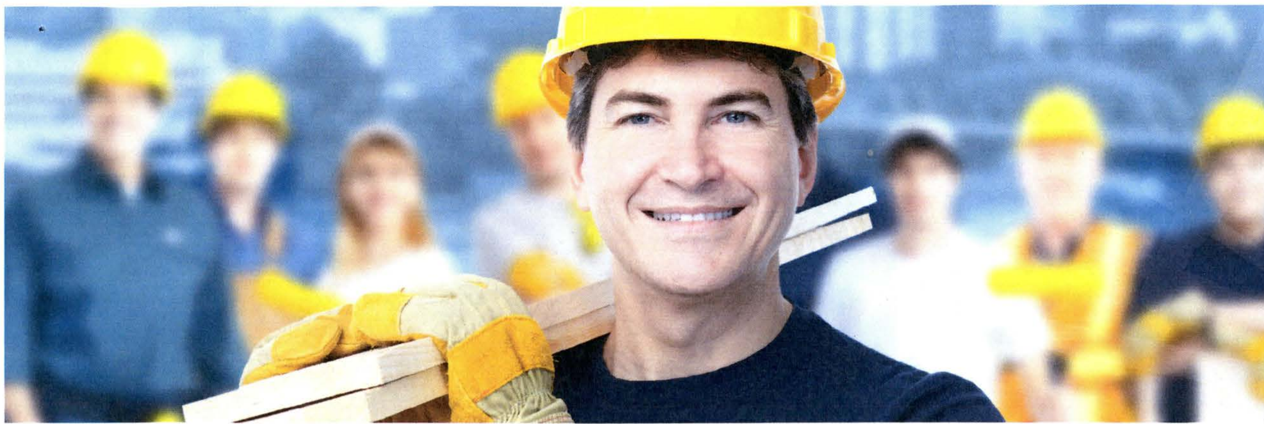
Modern pharmacy benefit management (PBM) emerged in the 1990s as a wave of new blockbuster prescription drugs came to market and the FDA opened the door to direct-to-consumer advertising. As drug utilization and costs skyrocketed in this era, payers demanded that PBMs develop innovative strategies to lower costs for patients and payers alike.

Today, PBMs help more than 266 million Americans access safe, affordable prescription drugs. PBMs negotiate price concessions from drug manufacturers and pharmacies; drive improvements in the quality of health outcomes for patients through drug adherence programs; and root out fraud, waste, and abuse across the system.



REDUCING PRESCRIPTION DRUG COSTS

Pharmacy benefit managers will save employers, unions, government programs, and consumers $654 billion over the next decade.[1]

PBMs reduce drug costs by:

- ✔ Promoting the use of generics and more affordable brand medications.
- ✔ Negotiating price concessions from drug manufacturers and drugstores.
- ✔ Offering clinical programs to drive medication adherence and health outcomes that address the nearly $300 billion in annual cost associated with non-adherence.
- ✔ Providing home delivery of prescription drugs and creating select networks of affordable pharmacies.
- ✔ Reducing fraud, waste, and abuse.

MEDICARE PART D

- » Medicare Part D plans are administered by PBMs and have 90% patient satisfaction.
- » PBMs negotiate significant discounts with drug manufacturers that help reduce Part D premiums, deductibles, and cost-sharing for beneficiaries.[2]
- » PBMs offer preferred pharmacy networks, which help reduce costs for nine out of ten seniors from urban, suburban, and rural areas.[3]
- » The Part D program has come in beneath CBO cost projections since its inception.
- » Part D monthly premiums have remained stable at around $34.[4]

On average, people with large employer coverage had pharmacy cost-sharing expenses of **$144 per person** in 2014, down from a recent high of $167 in 2009 (or about $185 in 2014 dollars).[5]

PBMs help patients and payers save **$941 per year** in prescription drug costs.[6]

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DESIGNING SOLUTIONS FOR EMPLOYERS, UNIONS, AND GOVERNMENT PROGRAMS

For over two decades, PBMs have delivered innovative solutions based on payer and patient needs. In the modern era of high priced and specialty drugs, payers continue to look to their PBMs for solutions to improve affordability, quality, and access for patients.

Payers rely on PBMs to:

- ✔ Ensure patients are treated with the right drug, at the right time, and at the right price.
- ✔ Encourage patients to make value-based decisions.
- ✔ Improve prescription drug adherence.
- ✔ Provide integrated care programs for patients with complex conditions.
- ✔ Develop high quality, affordable preferred pharmacy networks.
- ✔ Promote value-based benefit design that rewards drug makers for improved outcomes.
- ✔ Use medical benefit management programs to reduce wasteful spending.
- ✔ Promote appropriate and affordable sites of care.

95% of business owners and executives are satisfied with the company they've chosen to manage their prescription drug benefits.[7]

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DELIVERING HIGH PATIENT SATISFACTION AND IMPROVED OUTCOMES

- Nine in ten consumers are satisfied with their prescription drug benefits.[8]
- 75% of Medicare beneficiaries chose preferred pharmacies that offer convenient access and extra discounts at certain pharmacies.[9]
- PBMs and payers utilize programs that integrate patient-specific medical, pharmacy, and lab data to identify patients at highest risk for non-adherence.[10] Specialty pharmacies capitalize on this data by providing at-risk patients with highly personalized interventions to increase medication adherence and achieve improved clinical outcomes.
- PBMs use specialty pharmacies and data-driven utilization management programs to ensure that patients take the optimal doses of their medications. These tools have resulted in 11% overall savings for patients with hemophilia[11] and 8% savings for patients using immunoglobulin drugs.[12]
- In traditional retail pharmacies, pharmacist-patient consultations last an average of two minutes. In contrast, average clinical consultations at specialty pharmacies last 15 minutes. This explains why clinical care programs for patients with rheumatoid arthritis have resulted in 16% higher adherence over retail pharmacies, 23% few doctor's office visits, 9% fewer annual emergency room visits, and $1,797 in annual medical cost savings per patient.[13]

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IMPROVING PATIENT ACCESS, SAFETY, AND CONVENIENCE

PBMs develop and deliver patient-centric programs that lower prescription drug costs, improve quality and convenience.

- ✔ PBMs work with the country's 60,000+ pharmacies to ensure patient access to quality and safe pharmacy care.
- ✔ PBMs ensure patients get the right drugs at the right dosages to avoid dangerous and costly adverse drug events and hospitalizations.
- ✔ PBMs provide patients broad access to affordable prescription drug options.
- ✔ PBMs offer convenient home delivery of chronic medications.
- ✔ PBMs provide 24-7 access to specialty and mail-service pharmacy clinicians.
- ✔ PBMs promote cutting edge e-prescribing technology to reduce medication errors and prevent fraud.
- ✔ PBMs improve drug adherence and help patients manage medication side effects.
- ✔ PBMs work with high-risk patients and pharmacies to curb opioid abuse.

PREVENTING FRAUD, WASTE, AND ABUSE

PBMs deliver better pharmacy care and protect against fraud, waste, and abuse that adds costs to the system, while compromising patient safety and access.

- ✔ In PBM home delivery medication programs, less than 1% of all medications dispensed for Medicare beneficiaries are wasted. In comparison, two-thirds of medication wasted in Medicare is dispensed by drugstores.[14]
- ✔ Mail-service pharmacies are highly automated and able to quickly act on beneficiary information, therefore preventing unnecessary medications from being dispensed.
- ✔ PBMs design programs to minimize medication wastage that is from patient prescription filling patterns, the discontinuation of therapy, changed dosages, and other unexpected medication changes.
- ✔ PBMs provide doctors and patients access to cutting edge e-prescribing technology to reduce medication errors and prevent fraud.
- ✔ Diabetes patients under age 65 who used mail-service pharmacies had significantly fewer emergency room visits than those who picked up prescriptions at retail pharmacies.[15]
- ✔ PBMs prevent opioid abuse and drugstore shopping by working with high-risk patients to stop improper prescriptions from crossing the pharmacy counter.

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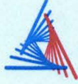

NOTES

[1] Visante, "Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers," February 2016. Estimated $654 billion savings relative to limited/low PBM management.

[2] CMS, Trustees Report & Trust Funds, 2016.

[3] Hart Research Associates, "A Survey of Seniors on Their Medicare Part D Preferred Pharmacy Network Plan," September 2014.

[4] CMS, Press Release: "Medicare projects relatively stable average prescription drug premiums in 2017," July 2016.

[5] Kaiser, "Examining high prescription drug spending for people with employer sponsored health insurance," October 2016.

[6] Visante, "The Return on Investment (ROI) on PBM Services," November 2016. Estimated $941 per patient per year savings relative to no PBM management.

[7] North Star Opinion Research, "Survey of Medium-to-Large Business Executives," July 26-29, 2016.

[8] Ayres, McHenry and Associates, Inc. "Key Findings from the National Consumer Survey of Adults with Prescription Drug Coverage," November 28-30, 2011.

[9] Drug Channels, "Medicare Part D 2016: 75% of Seniors in a Preferred Pharmacy Network (PLUS: Which Plans Won and Lost)," January 20, 2016.

[10] Express Scripts, "Leveraging Data to Keep Patients Safe," December 17, 2015.

[11] Magellan Rx, "An analysis on utilization trends and potential savings from dose optimization of antihemophilic factor products based on ideal body weight," 2016.

[12] Magellan Rx, "The impact of immunoglobulin utilization management and dose optimization in a regional health plan," 2016.

[13] Express Scripts Lab, "What's Special About Specialty Pharmacy?" July 8, 2015.

[14] Visante, "Myths and Realities of Medication Waste in Medicare Part D," March 2013.

[15] Am J Manag Care, "Safety and Effectiveness of Mail Order Pharmacy Use in Diabetes," November 2013.

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SB 2301 Mar 22, 2017 ECONOMIC (FINANCIAL) ADVANTAGE

1

married, and the community is generally aware of the living arrangement and the fact that the couple are not married.

▸ **single adultery.** (17c) Adultery in which only one of the persons is married.

adult offender. See OFFENDER.

Adult Protective Services. (1973) A governmental agency with responsibility for investigating allegations of elder abuse and neglect and for responding appropriately. • Every state has such an agency. — Abbr. APS. Cf. CHILD PROTECTIVE SERVICES.

ad usum et commodum (ad **yoo**-səm [*or* -zəm] et **kom**-ə-dəm), *adv.* [Law Latin] To the use and benefit.

ad valentiam (ad və-**len**-shee-əm), *adv.* [Law Latin] To the value.

ad valorem (ad və-**lor**-əm), *adj.* [Latin "according to the value"] (18c) (Of a tax) proportional to the value of the thing taxed. — **ad valorem,** *adv.*

ad valorem duty. See DUTY (4).

ad valorem tariff. See TARIFF (2).

ad valorem tax. See TAX.

advance, *n.* (17c) **1.** The furnishing of money or goods before any consideration is received in return. **2.** The money or goods furnished.

advance bill. See BILL (6).

advance cost. See COST (1).

advance-decline index. See INDEX (2).

advance directive. (1984) **1.** A document that takes effect upon one's incompetency and designates a surrogate decision-maker for healthcare matters. • The Uniform Health-Care Decisions Act (1993) states that the power of attorney for healthcare must be in writing and signed by the principal. Unless otherwise stated, the authority is effective only upon a determination that the principal lacks capacity, and it ceases to be effective once the principal regains his capacity. The agent must make decisions in accordance with the principal's relevant instructions, if there are any, or in the principal's best interests. — Also termed *power of attorney for healthcare*; *healthcare proxy*. See POWER OF ATTORNEY; UNIFORM HEALTH-CARE DECISIONS ACT. **2.** A legal document explaining one's wishes about medical treatment if one becomes incompetent or unable to communicate. — Often shortened to *directive*. — Also termed *medical directive*; *physician's directive*; *written directive*. See NATURAL-DEATH ACT; INSTRUCTION DIRECTIVE; PROXY DIRECTIVE. Cf. LIVING WILL. **3.** DO-NOT-RESUSCITATE ORDER.

advanced notice. See *advance notice* under NOTICE (3).

Advanced Television Enhancement Forum. A standard-setting organization that defines the protocols for HTML-based enhanced television. • The organization is an alliance of representatives from broadcast and cable networks, the consumer electronics and personal-computer industries, and television-transport companies. — Abbr. ATVEF.

advance-fee fraud. See FRAUD.

advancement, *n.* (15c) **1.** A payment to an heir (esp. a child) during one's lifetime as an advance share of one's estate, with the intention of reducing or extinguishing or diminishing the heir's claim to the estate under intestacy laws. • In some jurisdictions, the donor's intent is irrelevant if all the statutory elements of an advancement are present. A few jurisdictions define the relationship between the donor and donee to include inter vivos transfers between ancestors and descendants. — Also termed *preheritance*. See SATISFACTION (4). Cf. ADEMPTION.

> "It is sometimes difficult to know whether money which a parent has given to his child is an advancement or not, but, generally speaking, an advancement is money which is given either to start a child in life or to provide for him, and does not include casual payments, so that a child is not bound to account for every sum received from a parent." G.C. Cheshire, *Modern Law of Real Property* 784 (3d ed. 1933).

2. Progress or development in a person's job, skills, or level of knowledge. — **advance,** *vb.*

advance notice. See NOTICE (3).

advance payment. See PAYMENT (2).

advance premium. See PREMIUM (1).

advance pricing agreement. (1990) *Tax.* A usu. binding arrangement made between a multinational company and one or more national tax authorities about what method the company will use to calculate transfer prices. • The agreement's purpose is to reduce or eliminate double taxation. — Abbr. APA.

▸ **bilateral advance pricing agreement.** (1994) An advance pricing agreement made between a company and two tax authorities.

▸ **multilateral advance pricing agreement.** (1995) An advance pricing agreement made between a company and more than two tax authorities.

▸ **unilateral advance pricing agreement.** (2008) An advance pricing agreement made between a company and one tax authority. • This does not necessarily allow a company to avoid double taxation. A tax authority that is not a party to the agreement is not bound by the transfer-pricing method specified in the agreement.

advance sheets. (1868) A softcover pamphlet containing recently reported opinions by a court or set of courts. • Advance sheets are published during the interim between an opinion's announcement and its inclusion in a bound volume of law reports. Cf. *slip opinion* (1) under OPINION (1); REPORT (3).

> "As a bound volume of any series of reports is not published until sufficient matter has accumulated to fill it, it necessarily results in the holding of the first decisions rendered after the preceding volume has been issued, until there are enough more to justify the publication of the next volume. Even after enough material has been accumulated to fill a volume, there is necessarily considerable time consumed in its printing, indexing, and binding before the book is ready for delivery. Hence, it is customary, as soon as a part of the volume has come from the press, to issue such part in pamphlet form; and these paper-bound copies are known as 'advance sheets.' They are portions of the next volume issued in advance of final publication, being paged as they will appear in the bound volume. Advance sheets enable the enterprising lawyer to obtain the decisions right down almost to the date of his search for the law." Frank Hall Childs, *Where and How to Find the Law* 21 (1922).

advancing market. See *bull market* under MARKET.

advantage, *n.* (13c) **1.** A circumstance, ability, or condition that produces a superior position or state of being; superiority of state or position. **2.** Something that helps one to become more successful than others. **3.** The quality, state,

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or condition of possessing something that helps one to become more successful than others. **4.** A good or useful feature that something, such as a product, has. **5.** Any benefit or gain, esp. when derived from superiority of state or position. — **advantage,** *vb.* — **advantageous,** *adj.*

▸ **competitive advantage.** (1889) The potential benefit from information, ideas, or devices that, if kept secret by a business, might be economically exploited to improve the business's market share or to increase its income.

▸ **financial advantage.** The condition of being able to gain or of having more money than another. — Also termed *pecuniary advantage.*

▸ **pecuniary advantage.** See *financial advantage.*

advantaged, *adj.* (17c) Having more money, a better social position, etc. than someone else.

advantagium (ad-van-**tay**-jee-əm), *n.* [Law Latin] *Hist.* An advantage.

advena (**ad**-və-nə), *n.* [Latin] *Roman law.* Someone who has come from abroad, esp. for a temporary stay; a sojourner.

adventitia bona (ad-ven-**tish**-ee-ə **boh**-nə). See BONA ADVENTITIA.

adventitia dos (ad-ven-**tish**-ee-ə dohs), *n.* [Latin] *Civil law.* A dowry given by someone other than the wife's paterfamilias. Pl. ***adventitiae dotes.***

adventitious property. See PROPERTY.

ad ventrem inspiciendum (ad **ven**-trəm in-spish-ee-**en**-dəm), *n.* [Latin] See DE VENTRE INSPICIENDO.

adventura (ad-ven-**t[y]oor**-ə), *n.* [Law Latin] *Hist.* An adventure. • Flotsam, jetsam, and lagan were styled *adventurae maris* ("adventures of the sea").

adventure. (17c) **1.** A commercial undertaking that has an element of risk; a venture. Cf. JOINT VENTURE. **2.** *Marine insurance.* A voyage involving financial and insurable risk, as to a shipment of goods. — Often shortened to *venture.*

▸ **common adventure.** (17c) A maritime enterprise, characterized as an undertaking in which all participants, including the carrier, everyone with an interest in the cargo, and the insurers, share the risks of the perils of the sea. • The principle of shared risk is fundamental to maritime law. — Also termed *joint adventure; common venture.*

▸ **gross adventure.** (17c) A loan on bottomry, so called because the lender will be liable for the gross (or general) average. See BOTTOMRY.

▸ **joint adventure.** (17c) **1.** See *common adventure.* **2.** See JOINT VENTURE.

adventurer. (17c) Someone who undertakes a hazardous action or enterprise; one with a stake in a commercial adventure.

ad verecundiam. See *argumentum ad verecundiam* under ARGUMENTUM.

adversarial, *adj.* Involving or characterized by dispute or a clash of interests. — **adversary,** *n.*

adversarius (ad-vər-**sair**-ee-əs), *n.* [Latin] *Roman law.* An adversary in a lawsuit.

adversary (**ad**-vər-ser-ee), *n.* (14c) An opponent; esp., opposing counsel. — Also termed *opposition.* — **adversary,** *adj.*

adversary procedure. See ADVERSARY SYSTEM.

adversary proceeding. (1744) **1.** A hearing involving a dispute between opposing parties <Judge Adams presided over the adversary proceeding between the landlord and tenant>. **2.** *Bankruptcy.* A lawsuit that is brought within a bankruptcy proceeding, governed by special procedural rules, and based on conflicting claims usu. between the debtor (or the trustee) and a creditor or other interested party <the Chapter 7 trustee filed an adversary proceeding against the party who received $100,000 from the debtor one week before the bankruptcy filing>.

adversary system. (1936) A procedural system, such as the Anglo-American legal system, involving active and unhindered parties contesting with each other to put forth a case before an independent decision-maker. — Also termed *adversary procedure;* (in criminal cases) *accusatorial system; accusatory procedure.* Cf. INQUISITORIAL SYSTEM.

> "The term *adversary system* sometimes characterizes an entire legal process, and sometimes it refers only to criminal procedure. In the latter instance, it is often used interchangeably with an old expression of continental European origin, 'accusatorial procedure,' and is juxtaposed to the 'inquisitorial,' or 'nonadversary,' process. There is no precise understanding, however, of the institutions and arrangements denoted by these expressions." Mirjan Damaska, "Adversary Procedure," in 1 *Encyclopedia of Crime and Justice* 24, 24–25 (Sanford H. Kadish ed., 1983).

adverse, *adj.* (15c) **1.** Against; opposed (to). **2.** Having an opposing or contrary interest, concern, or position. **3.** Contrary (to) or in opposition (to). **4.** HOSTILE.

adverse action. (18c) A decision or event that unfavorably affects a person, entity, or association. • Common examples of adverse actions include a decrease in one's pay by an employer or a denial of credit by a lender.

adverse-agent doctrine. (1954) The rule that an agent's knowledge will not be imputed to the principal if the agent is engaged in fraudulent activities that are concealed as part of the fraud. See DOCTRINE OF IMPUTED KNOWLEDGE.

adverse authority. See AUTHORITY (4).

adverse-domination doctrine. (1989) The equitable principle that the statute of limitations on a breach-of-fiduciary-duty claim against officers and directors (esp. a corporation's action against its own officers and directors) is tolled as long as a corporate plaintiff is controlled by the alleged wrongdoers. • The statute is tolled until a majority of the disinterested directors discover or are put on notice of the claim against the wrongdoers. The purpose of this doctrine is to prevent a director or officer from successfully hiding wrongful or fraudulent conduct during the limitations period. *FDIC v. Shrader & York,* 991 F.2d 216, 227 (5th Cir. 1993). This doctrine is available only to benefit the corporation. — Also termed *adverse dominion; doctrine of adverse domination.*

adverse dominion. 1. ADVERSE-DOMINATION DOCTRINE. **2.** *Rare. Torts.* The unlawful exercise of authority or control over goods so that the true owner is dispossessed. See CONVERSION (2). **3.** *Rare.* ADVERSE POSSESSION (1).

adverse easement. See *prescriptive easement* under EASEMENT.

> "The chief of police of a New England town once declared to the press that he believed in a strict curfew law, 'selectively enforced.' 'Selective enforcement' in this case means that the policeman decides for himself who ought to be sent home from the street; legislative candour would suggest that if this is the intention it ought to be expressed in the law itself, instead of being concealed behind words that are 'strict' and categorical." Lon L. Fuller, *Anatomy of the Law* 42 (1968).

selective incorporation. See INCORPORATION (2).

selective prosecution. (1967) **1.** SELECTIVE ENFORCEMENT. **2.** The practice or an instance of a criminal prosecution brought at the discretion of a prosecutor rather than one brought as a matter of course in the normal functioning of the prosecuting authority's office. • Selective prosecution violates the Equal Protection Clause of the Fourteenth Amendment if a defendant is singled out for prosecution when others similarly situated have not been prosecuted and the prosecutor's reasons for doing so are impermissible.

selective prospectivity. See PROSPECTIVITY.

Selective Service System. The federal agency that registers all persons 18–26 who are eligible for military service military service and provides personnel to the Armed Forces during emergencies. • It was established in 1940 as a part of the War Manpower Commission and became independent in 1943. — Abbr. SSS.

selective waiver. See WAIVER (2).

selectman. (17c) A municipal officer elected annually in some New England towns to transact business and perform some executive functions.

self-applying, *adj.* (1894) (Of a statute, ordinance, etc.) requiring no more for interpretation than a familiarity with the ordinary meanings of words.

self-authenticating will. See *self-proved will* under WILL.

self-authentication. See AUTHENTICATION.

self-canceling installment note. See NOTE (1).

self-certification. (1951) The signing of a form or note to verify that one has done something or to explain why one has not done something.

self-crimination. See SELF-INCRIMINATION.

self-critical-analysis privilege. See PRIVILEGE (3).

self-dealing, *n.* (1940) Participation in a transaction that benefits oneself instead of another who is owed a fiduciary duty. • For example, a corporate director might engage in self-dealing by participating in a competing business to the corporation's detriment. Cf. FAIR DEALING (1), (2). — **self-deal,** *vb.*

self-declared trust. See TRUST (3).

self-defense, *n.* (1651) **1.** The use of force to protect oneself, one's family, or one's property from a real or threatened attack. • Generally, a person is justified in using a reasonable amount of force in self-defense if he or she reasonably believes that the danger of bodily harm is imminent and that force is necessary to avoid this danger. — Also termed *defense of self.* Cf. *adequate provocation* under PROVOCATION.

> "The law of self-defence, as it is applied by the courts, turns on two requirements: the force must have been necessary, and it must have been reasonable." Andrew Ashworth, *Principles of Criminal Law* 114 (1991).

▸ **anticipatory self-defense.** (1946) See *preemptive self-defense.*

▸ **imperfect self-defense.** (1882) *Criminal law.* A good-faith but ultimately mistaken belief, acted on by a criminal defendant, that self-defense is necessary to repel an attack. • In some jurisdictions, such a self-defender will be charged with a lesser offense than the one committed.

▸ **perfect self-defense.** (1883) The use of force by one who accurately appraises the necessity and the amount of force to repel an attack.

▸ **preemptive self-defense.** (1969) An act of aggression by one person or country to prevent another person or country from pursuing a particular course of action that is not yet directly threatening but that, if permitted to continue, could result at some future point in an act of aggression against the preemptive actor. • In domestic-relations law, the phrase refers to the use of force to prevent another person from taking possibly lethal action against oneself. It is disfavored in the law. — Also termed *anticipatory self-defense* (ASD); *preventive self-defense.*

▸ **preventive self-defense.** See *preemptive self-defense.*

2. *Int'l law.* The right of a state to defend itself against a real or threatened attack. *See* United Nations Charter, art. 51 (59 Stat. 1031). — Also spelled (esp. BrE) *self-defence.* — **self-defender,** *n.*

> "Self-defence, properly understood, is a legal right, and as with other legal rights the question whether a specific state of facts warrants its exercise is a legal question. It is not a question on which a state is entitled, in any special sense, to be a judge in its own cause." J.L. Brierly, *The Law of Nations* 319 (5th ed. 1955).

self-destruct clause. A provision in a trust for a condition that will automatically terminate the trust. • Discretionary trusts, esp. supplemental-needs trusts, often include a self-destruct provision. For example, a trust to provide for the needs of a disabled person may terminate if the beneficiary becomes ineligible for a government-benefits program such as Medicaid.

self-destruction. See SUICIDE (1).

self-determination. *Int'l law.* The right of each culturally homogeneous country to constitute an independent state. See RIGHT OF SELF-DETERMINATION FOR PEOPLES.

> "The political origins of the modern concept of self-determination can be traced back to the Declaration of Independence of the United States of America of 4 July 1776, which proclaimed that governments derived 'their just powers from the consent of the governed' and that 'whenever any Form of Government becomes destructive to these ends, it is the Right of the People to alter or to abolish it.' The principle of self-determination was further shaped by the leaders of the French Revolution, whose doctrine of popular sovereignty, at least initially, required renunciation of all wars of conquest and contemplated annexations of territory to France only after plebiscites." Daniel Thürer & Thomas Burri, "Self-Determination," in 9 *The Max Planck Encyclopedia of Public International Law* 113, 114 (Rüdiger Wolfrum ed., 2012).

self-determination contract. See CONTRACT.

self-determination election. See GLOBE ELECTION.

self-disserving declaration. *Hist.* See *declaration against interest* under DECLARATION (6).

self-employed retirement plan. See KEOGH PLAN.

FAIR COMPETITION

failure to claim. See FAILURE.

failure to comply. See FAILURE.

failure to depart. See FAILURE.

failure-to-disclose-best-mode rejection. See REJECTION.

failure to file return. See FAILURE.

failure to make delivery. See FAILURE.

failure to meet obligations. 1. See BANKRUPTCY (1). **2.** See INSOLVENCY.

failure to perform. See FAILURE.

failure-to-perform exclusion. See EXCLUSION (3).

failure to protect. See FAILURE.

failure to state a cause of action. See *failure to state a claim upon which relief can be granted* under FAILURE.

failure to state a claim upon which relief can be granted. See FAILURE.

failure-to-supervise statute. See PARENTAL-LIABILITY STATUTE.

failure to testify. See FAILURE.

failure to thrive. (1967) *Family law.* **1.** A medical and psychological condition in which a child's height, weight, and motor development fall significantly below average growth rates. • Failure to thrive is sometimes asserted as a ground for alleging abuse or neglect by a parent or caregiver. **2.** A condition, occurring during the first three years of a child's life, in which the child suffers marked retardation or ceases to grow. — Abbr. FTT.

failure to warn. See FAILURE.

faint action. See FEIGNED ACTION.

faint pleader. (17c) A false, fraudulent, or collusive manner of pleading.

fair, *adj.* (bef. 12c) **1.** Characterized by honesty, impartiality, and candor; just; equitable; disinterested <everyone thought Judge Reavley to be fair>. **2.** Free of bias or prejudice <in jury selection, the lawyers tried to select a fair and impartial jury>. **3.** (Of an interpretation or reading) compellingly plausible based on the words of the legal instrument at issue. See FAIR READING. **4.** (Of a document) unblemished and unaltered <fair copy>. **5.** (Of an object considered for its value) reasonably good in kind, quality, or degree; free from any pronounced defect.

fair, *n.* (13c) *Hist.* A privileged market for the buying and selling of goods. • A fair was an incorporeal hereditament granted to a town by royal patent or franchise or established by prescription. The franchise to hold a fair conferred important privileges, and a fair, as a legally recognized institution, possessed distinctive legal characteristics, most of which are now obsolete. Cf. *market overt* under MARKET.

Fair and Accurate Credit Transactions Act. A 2003 amendment to the federal Fair Credit Reporting Act providing for free annual credit reports to consumers and establishing measures intended to help prevent identity theft. • One of the Act's better-known and more heavily litigated provisions prohibits merchants from printing the expiration date or more than the last five digits of the card number on a point-of-sale credit-card or debit-card receipt. 15 USCA § 1681c(g). — Abbr. FACTA; FACT Act.

fair-and-equitable requirement. (1970) *Bankruptcy.* A Bankruptcy Code standard requiring a forced, nonconsensual Chapter 11 plan (a "cramdown" plan) to provide adequately for each class of interests that has not accepted the plan. • In determining whether a cramdown plan is fair and equitable, a bankruptcy court must apply the Code's detailed statutory criteria, consider the plan as a whole, and weigh all the circumstances surrounding the treatment of each impaired class of interests. 11 USCA § 1129(b). See CRAMDOWN.

fair and impartial jury. See *impartial jury* under JURY.

fair and impartial trial. See FAIR TRIAL.

fair and proper legal assessment. See EQUALIZATION (2).

fair and reasonable value. See *fair market value* under VALUE (2).

fair and valuable consideration. See *fair consideration* (1) under CONSIDERATION (1).

fair averaging. 1. A method of consolidating items based on technically and statistically valid data, esp. for determining flat grant amounts paid to recipients of general assistance programs where the grant amounts are based on the actual subsistence needs of the recipients. **2.** The process or activity of assessing taxes by using the average of the amount and price of goods acquired over a 12-month period rather than the amount and price at a particular time of year.

fair cash market value. See *fair market value* under VALUE (2).

fair cash value. See *fair value* under VALUE (2).

fair comment. (18c) A statement based on the writer's or speaker's honest opinion about a matter of public concern. • Fair comment is a common-law defense to libel or slander. For a statement to be considered a fair comment, it must be based on facts truly stated, it must be free from the imputation of corrupt or dishonorable motives on the part of the person whose conduct is criticized (except to the extent that the imputation is warranted by the facts truly stated), and it must be the honest statement of the writer's or speaker's real opinion.

fair competition. See COMPETITION.

fair consideration. See CONSIDERATION (1).

fair construction. See FAIR READING.

Fair Credit Billing Act. A federal statute that protects consumers from unfair billing practices, facilitates the correction of billing errors by credit-card companies, and makes those companies more responsible for the quality of goods purchased by cardholders. 15 USCA §§ 1666–1666j. — Abbr. FCBA.

Fair Credit Reporting Act. (1970) A 1970 federal statute that regulates disclosure and use of consumer-credit information and ensures the right of consumers to have access to and to correct their credit reports. 15 USCA §§ 1681–1681u. • Many states have enacted similar statutes. — Abbr. FCRA.

fair-cross-section requirement. (1975) *Constitutional law.* The principle that a person's right to an impartial jury, guaranteed by the Sixth Amendment, includes a requirement that the pool of potential jurors fairly represent the composition of the jurisdiction's population. • Although the pool of potential jurors need not precisely match the

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competition. (16c) The struggle for commercial advantage; the effort or action of two or more commercial interests to obtain the same business from third parties.

▸ **fair competition.** (17c) Open, equitable, and just competition between business competitors.

▸ **horizontal competition.** (1930) Competition between a seller and its competitors. • The Sherman Antitrust Act prohibits unreasonable restraints on horizontal competition, such as price-fixing agreements between competitors. — Also termed *primary-line competition.*

▸ **perfect competition.** (1884) A completely efficient market situation characterized by numerous buyers and sellers, a homogeneous product, perfect information for all parties, and complete freedom to move in and out of the market. • A perfectly competitive market is one in which no single firm has influence on the price of what it sells. Perfect competition rarely if ever exists, but antitrust scholars often use the concept as a standard for measuring market performance.

▸ **primary-line competition.** See *horizontal competition.*

▸ **secondary-line competition.** See *vertical competition.*

▸ **unfair competition.** See UNFAIR COMPETITION.

▸ **vertical competition.** (1954) Competition between participants at different levels of distribution, such as manufacturer and distributor. — Also termed *secondary-line competition.*

competition law. See ANTITRUST LAW (1).

competitive advantage. See ADVANTAGE.

competitive advertising. See ADVERTISING.

competitive bid. See BID (2).

competitive civil-service examination. (1897) A test designed to evaluate a person's qualifications for a civil-service position. • This type of examination may be open to all those seeking civil-service employment, or it may be restricted to those civil servants seeking a promotion. See CIVIL SERVICE.

competitive injury. A wrongful economic loss caused by a commercial rival, such as the loss of sales due to unfair competition; a disadvantage in a plaintiff's ability to compete with a defendant, caused by the defendant's unfair competition. • Most courts require that the plaintiff suffer a competitive injury in order to prevail in a misappropriation action or to have standing to prosecute a false-advertising action under 15 USCA § 1125(a)(1)(B). — Also termed *competitive harm.*

competitive seniority. See SENIORITY.

competitor click fraud. See FRAUD.

compilation (kom-pə-**lay**-shən), *n.* (15c) **1.** *Copyright.* A collection of literary works arranged in an original way; esp., a work formed by collecting and assembling preexisting materials or data that are selected, coordinated, or arranged in such a way that the resulting product constitutes an original work of authorship. • An author who creates a compilation owns the copyright of the compilation but not of the component parts. *See* 17 USCA § 101. Cf. *collective work, derivative work* under WORK (2). **2.** A collection of statutes, updated and arranged to facilitate their use. — Also termed *compiled statutes.* **3.** A financial statement that does not have an accountant's assurance of conformity with generally accepted accounting principles. • In preparing a compilation, an accountant does not gather evidence or verify the accuracy of the information provided by the client; rather, the accountant reviews the compiled reports to ensure that they are in the appropriate form and are free of obvious errors. — **compile,** *vb.*

compiled statutes. 1. See COMPILATION (2). **2.** See STATUTE.

complainant (kəm-**playn**-ənt). (15c) **1.** The party who brings a legal complaint against another; esp., the plaintiff in a court of equity or, more modernly, a civil suit.

> "A suit in equity, under the procedure of the English Court of Chancery, which was generally adopted in the American States prior to the code, is instituted by the plaintiff filing a bill of complaint. The plaintiff is usually called the complainant, in the Federal courts the complainant or plaintiff indifferently. The bill is in substance a petition to the chancellor, or judge of the court of equity, setting forth at large the grounds of the suit, and praying the process of the court, its subpoena, to bring the defendant into court and compel him to answer the plaintiff's bill, and, also, for such relief by decree or interlocutory remedy, by way of injunction, etc., as the plaintiff supposes himself entitled to." Edwin E. Bryant, *The Law of Pleading Under the Codes of Civil Procedure* 55 (2d ed. 1899).

2. Someone who, under oath, signs a statement (called a "complaint") establishing reasonable grounds to believe that some named person has committed a crime. — Also termed *affiant.*

complainantless crime. See *victimless crime* under CRIME.

complaint. (14c) **1.** The initial pleading that starts a civil action and states the basis for the court's jurisdiction, the basis for the plaintiff's claim, and the demand for relief. • In some states, this pleading is called a *petition.* **2.** *Criminal law.* A formal charge accusing a person of an offense. Fed. R. Crim. P. 3. Cf. INDICTMENT; INFORMATION.

▸ **amended complaint.** (1822) A complaint that modifies and replaces the original complaint by adding relevant matters that occurred before or at the time the action began. Fed. R. Civ. P. 15(d). • In some circumstances, a party must obtain the court's permission to amend its complaint. Fed. R. Civ. Pro. 15(a). — Also termed *substituted complaint.* Cf. *supplemental complaint.*

▸ **complaint for modification.** See *motion to modify* under MOTION (1).

▸ **counter-complaint.** (18c) A complaint filed by a defendant against the plaintiff, alleging that the plaintiff has committed a breach and is liable to the defendant for damages.

▸ **criminal complaint.** (17c) A formal charging instrument by which a person is accused of a crime, usu. a misdemeanor or violation in a sworn statement.

▸ **first complaint.** See FRESH COMPLAINT.

▸ **fresh complaint.** See FRESH COMPLAINT.

▸ **preliminary complaint.** (1833) A complaint issued by a court to obtain jurisdiction over a criminal suspect for a hearing on probable cause or on whether to bind the suspect over for trial.

▸ **short-form complaint.** (1911) A simplified, convenient, indorsed complaint typically used by pro se litigants. • As contrasted with a formal complaint, a short-form complaint may be used in certain actions normally requiring the use of a formal complaint, but may be

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2. Every banking institution must keep an adequate record of all pending litigation to which it is a party in concerning its exercise of fiduciary powers.
3. A banking institution must retain the records required for a period of three years from the later of the termination of the fiduciary account relationship to which the records relate or of litigation relating to the account.

6-05.2-04. Audit of trust activities.

A committee of directors, exclusive of any active officers of the bank, must, at least once during each calendar year and within fifteen months of the last audit, make suitable audits of the trust activities or cause suitable audits to be made by auditors responsible to the board of directors, and must ascertain whether the trust activities have been administered in accordance with law and sound fiduciary principles. The board of directors may, instead of the periodic audit, adopt an adequate continuous audit system. A report of the audits and examination required under this section, together with any action taken, must be noted in the minutes of the board of directors.

6-05.2-05. Uninvested or undistributed funds.

Uninvested or undistributed funds held by a banking institution in a fiduciary capacity must not be held uninvested or undistributed any longer than is reasonable for the proper management of the account. Each banking institution exercising fiduciary powers must adopt and follow written policies and procedures intended to ensure that the maximum rate of return available for trust-quality, short-term investments is obtained consistent with the requirements of the governing instrument or law. The policies and procedures must take into consideration all relevant factors, including the anticipated return that could be obtained while the cash remains uninvested or undistributed, the cost of investing the funds, and the anticipated need for the funds.

6-05.2-06. Self-dealing.

1. Funds held by a banking institution as fiduciary may not be invested in stock or obligations of, or property acquired from, the banking institution or its directors, officers, or employees, or individuals with whom there exists such a connection, or organizations in which there exists such an interest, as affects the exercise of the best judgment of the banking institution in acquiring the property, or in stock or obligations of, or property acquired from, affiliates of the banking institution or their directors, officers, or employees, unless authorized by the instrument creating the relationship or as authorized by law.
2. Property held by a banking institution as fiduciary may not be sold or transferred, by loan or otherwise, to the banking institution or its directors, officers, or employees, or to individuals with whom there exists such a connection, or organizations in which there exists such an interest, as affects the exercise of the best judgment of the banking institution in selling or transferring the property, or to affiliates of the banking institution or their directors, officers, or employees except:
   a. As authorized by the instrument creating the relationship or as authorized by law;
   b. When the banking institution has been advised in writing by its counsel or auditor that it has incurred as a fiduciary a contingent or potential liability and desires to relieve itself of that liability, a sale or transfer may be made with the approval of the board of directors, provided that the banking institution, upon consummation of the sale or transfer, makes reimbursement in cash at no loss to the account;
   c. To purchase at market value, defaulted investment funds; or
   d. Where ordered by the board.
3. Funds held by a banking institution as fiduciary may not be invested by the purchase of stock or obligations of the banking institution or its affiliates unless authorized by the instrument or as authorized by law. If the retention of stock or obligations of the banking institution or its affiliates is authorized by the instrument creating the relationship, by court order, or by law it may exercise rights to purchase its own stock

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or securities convertible into its own stock when offered pro rata to stockholders. When the exercise of rights or receipt of a stock dividend results in fractional share holdings, additional fractional shares may be purchased to complement the fractional shares so acquired.

4. A banking institution may sell assets held by it as fiduciary in one account to itself as fiduciary in another account if the transaction is fair to both accounts and if the transaction is not prohibited by the terms of any governing instrument.
5. A banking institution may make a loan to an account from the funds belonging to another account when the making of a loan to a designated account is authorized by the instrument creating the account from which the loan is made.
6. A banking institution may make a loan to an account and may take, as security for the loan, assets of the account provided the transaction is fair to the account.

6-05.2-07. Custody of investments.

1. The investment of each account must be kept separate from the assets of the banking institution and must be placed in the joint custody or control of not less than two of the officers or employees of the banking institution designated for that purpose by the board of directors or by one or more officers designated by the board. The banking institution may permit the investments of a fiduciary account to be deposited elsewhere.
2. Except for commingled investments, the investments of each account must be kept separate from those of all other accounts or adequately identified as the property of the relevant account.

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Amendment to Bill LC# 17.0928.03000

Prepared by Legislative Intern 8
March 22, 2017

PROPOSED AMENDMENT TO SENATE BILL NO. 2301

Page 1, after line 9, insert "a. "Firewall" means a written policy that precludes one person from sharing information with another person."

Page 1, line 10, replace "a." with "b."

Page 1, line 11, replace "b." with "c."

Page 1, line 12, replace "c." with "d."

Page 1, line 18, replace "d." with "e."

Page 2, line 2, remove "agrees to fair competition, no self-dealing, and no interference"

Page 2, line 3, remove "with prospective economic advantage and"

Page 2, line 4, after "functions" insert ","

Page 2, line 4, remove "and"

Page 2, line 4, after "pharmacy" insert ", and patient assistance program"

Renumber accordingly

Subsection 3 will now read as follows:

3. A pharmacy benefits manager or a pharmacy benefits manager's affiliates or subsidiaries may not own or have an ownership interest in a patient assistance program and a mail order specialty pharmacy, unless the pharmacy benefits manager, affiliate, or subsidiary establishes a firewall between the administrative functions, the mail order pharmacy, and the patient assistance program.