



## **2016 Point of Sale (POS) Pilot Event**

**January 21, 2016, 1:00 PM – 2:30 PM EST**

**Audio Conference Transcript**

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**Audio Introduction**  
*InterCall Conference Operator*

Operator: Good afternoon. And welcome to today's conference call.

After the speakers' remarks, there will be a question and answer session. At that time if you would like to ask a question, press star, then the number 1 on your telephone keypad. To withdraw your question, press the pound key.

When asking your question, please state your name and the name of the speaker you are directing your question to.

Thank you. I would now like to turn the call over to Stacey Plizga. Please go ahead.

**Welcome**

*Stacey Plizga – Moderator, Provider Resources, Inc.*

Stacey Plizga: Good afternoon, everyone. Thank you for joining the Part D Point of Sale Pilot Conference Call that is originating from the CMS Central Office in Baltimore, Maryland.

We have representatives with us today from Highmark, CVS, Martin's Point and PerformRx who will be sharing information with you today.

We welcome your participation. There will be an opportunity at the end of the discussion for questions and comments.

We will not be taking comments or questions during the speaker presentation. Due to time constraints, attendees will be limited to one question.

Additional questions can be sent to the POS pilot at CMS.hhs.gov mailbox. Kicking things off for us today, we have Cynthia Tudor, the Deputy Center Director for the Center of Medicare.

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## Opening Remarks

*Cynthia G. Tudor, PhD – Deputy Center Director, Center for Medicare*

Cynthia Tudor: Good afternoon. Thank you for joining today's call.

In the 2016 call letter, CMS indicated we would conduct a pilot in response to concerns raised about beneficiary access to the coverage and appeals process after they experienced a rejected Part D claim at the point of sale.

The overall goal of the pilot was to help identify options for resolving certain claims rejections without the beneficiary having to request a coverage determination from their plan.

Over the past several months we've conducted this pilot with four groups, and we're enjoying the experience in learning about ways to help beneficiaries access their Part D benefits.

CMS invited the Part D plans and PBMs that participated in the pilot to come together today to share their experiences and ideas with other plans and Part D stakeholders. And we want to thank them for their excellent work on this project and for being available to speak with you all.

Today's speakers were invited to provide an overview of their work and highlight notable takeaways, including a description of their outreach process and how they identified targeted drugs; findings from the cases they worked on; benefits from this process as well as challenges they encountered; how such a process might be operationalized in response to a potential CMS policy change, and other ways Part D plans may be able to proactively address point of sale issues without the beneficiary having to take action, including improving prescriber awareness of plan formularies.

Before I turn the discussion over to them, I'd like to acknowledge the CMS staff who worked on this project.

From CMS, I'd like to thank Dr. Jeffrey Kelman, our Chief Medical Officer. From the Division of Appeals Policy, I'd like to thank Beckie Peyton who has been a champion of this from the time we started; Amber Casserly,

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Kathryn McCann-Smith and Rita Wurm, from the division of Part D Policy, Stephanie Hammonds and Craig Miner from the Division of Formulary Benefit Operations, Brian Martin and Anna Polk, and from the Division of Clinical and Operational Performance, Alice Lee-Martin.

With that, I will turn this over to Stacey. Thank you all for participating.

Stacey Plizga: Thank you, Cynthia. Next, from Highmark we will be hearing from Tom Boettler, who is the Director of Government Compliance, and Ryan Cox the Director of Clinical Pharmacy Services.

**Highmark, Inc.**

*Thomas Boettler – Director, Government Compliance*

*Ryan Cox – Director, Clinical Pharmacy Services*

Tom Boettler: Thank you, Stacey. Good morning, everyone.

As Stacey mentioned, my name is Tom Boettler. I am the Director of Government Compliance for Highmark, and joining me this morning is Ryan Cox who's our Director of Clinical Pharmacy Services at Highmark.

Before we begin this morning, I wanted to just take the opportunity to thank CMS for the opportunity to participate in the pilot as well as present our findings with the other participants in the pilot this morning.

We found this pilot to be very, very beneficial to us. And we hope that CMS also finds our results very useful when helping develop future policy changes.

Before we get started, we wanted to just go through and familiarize everyone with Highmark and who we are.

So on slide 3, just as some background information, Highmark Health. We are an interdependent, integrated healthcare delivery financing system which consists of three business units; our Highmark Inc. which is our health plan; Allegheny Health Network, which is our health system or our provider network in Western Pennsylvania, and HM Health Solutions, which is our IT company that supports and operates our claims processing platform as well as a number of other IT assets within the company.

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Overall, we employ 35,000 individuals across 50 states in the United States of America.

On the health plan side of the business, we operate insurance plans in Pennsylvania, West Virginia and Delaware. And we serve approximately 5.3 million members, and we are the fourth largest Blue Cross Blue Shield-affiliated organization.

In the health plan business, we also have a number of what we term diversified businesses that offer supplemental products, such as United Concordia dental, which is our dental insurance business; HM Insurance Group, which is our stop-loss business; Davis Vision, which is our eye insurance arm, as well as Visionworks, which are our vision retail outlets.

From the Medicare Advantage perspective, we introduced our HMO product back in 1995. We have grown that original product to approximately 317,000 MA members currently across an HMO plan and various PPO plans.

We also have approximately 40,000 members in our prescription drug plan as well as 85,000 members that are receiving supplemental benefits as well.

So now I'm going to hand it over to Ryan just to introduce you to the drugs that we included in the pilot as well as some of the factors that we considered as we were thinking through how we wanted to build out the pilot program.

Ryan?

Ryan Cox: Thank you, Tom. I appreciate the introduction. As noted, when presented with the opportunity to participate in the point of sale retail pilot program, we began by looking at our rejected claims – particularly the experience that we were seeing with our current membership in calendar year or contract year 2015 – and looked at rates of rejection. And particularly rates of rejection where we did not see a significant uptick in follow up tilts—particularly in critical conditions.

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So we actually focused in on asthma and COPD. We excluded certain things right off the bat. So, like high-risk medications. We excluded opioids. And we also excluded drugs that have significantly high off-label utilization.

So again, looking at trying to improve access to the beneficiaries to something that's going to actually help prevent hospitalization and help prevent, you know, a continued advancement of their disease.

So we did choose non-formulary products for COPD and for asthma, and we threw in a PPI just for kicks because there are so many generics available for that one.

But the focus was primarily within that category. Because, for whatever reason, we were seeing a significantly high number of rejects within that particular category.

So I will turn it back over to Tom, and he's going to go over some of the specifics within the program itself.

Tom Boettler: Thank you, Ryan.

On slide 5, it's just a basic overview of what our pilot process looks like. And this is probably a little bit oversimplified. But really, we rolled out a four-step process for the pilot.

So through the length of the entire pilot, each week we identified rejected claims for the medications that Ryan just discussed.

From that sample, we then moved on to Step 2, and we reviewed the member's history. So we looked to see if the member had a coverage determination that was already in process. Or did they have paid claims that would allow us to forego the coverage determination process and provide the member the medication?

If both of those did not occur – so the member did not have a paid claims history that we could look at, or if there was not a coverage determination in

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process – these members we targeted as good examples to move forward with reaching out and seeing if we could facilitate a formulary alternative.

So in those instances, we then initiated a call to the provider to see if they would be willing to prescribe a formulary alternative. If so, then we worked with the prescriber to send that script over to the pharmacy, where the member originally received their rejection.

And then we also initiated a call to the members to let them know that their medication was available for pickup.

On the back end, Step 4, we monitored for paid claims. And if we didn't see a paid claim come through, we then worked with the pharmacy to see if they had come to pick it up, or if there was any other extenuating circumstance for the member.

And moving on to slide 6, slide 6 really gives you a good understanding of the volume of cases that we worked through and the results of where we landed with the pilot. Overall, we believe that the pilot was very, very successful. And you can see this by the pictorial on the left hand side of the screen.

So from a volume perspective, we worked through 33 cases during the course of the pilot. And in 73 percent of those cases, we were able to actually prescribe a formulary alternative.

Only nine instances were we not able to do that. Of those nine instances, the provider still wanted to go through and work through a coverage determination. And in five instances, there were other circumstances that prohibited us from moving forward with an alternative or a coverage determination.

Specifically, the member may have been receiving samples from their prescriber. Or, there were other circumstances where the member did not require the medication going forward.

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Overall – that was the goal we set out at the beginning of the pilot was to facilitate either a formulary alternative or to forego the coverage determination process in a lot of the members who received the medication.

Another interesting fact is if you look at the right hand side of the screen, how did that really translate into pills or medication adherence?

While the numbers there are a little bit less favorable than we would have liked to have seen, it was about 50-50 percent pickup rate from the pharmacy itself. So we still believe that overall, the pilot showed very favorable results in getting the prescriber to prescribe a formulary alternative. That's just from a medication adherence perspective. We didn't see the (inaudible) we would have liked.

So now I'm going to turn it back over to Ryan to just walk through some of the operational successes and some of the challenges that we faced as we were executing the pilot.

Ryan Cox:

So on slide 7, I'm going to review what we determined as our – what we considered successes and what we would consider our challenges in rolling out this program.

So as Tom noted, we had several successes. We felt that the stakeholders were engaged from the provider side. We were granting access to medication to our beneficiaries, particularly in a critically ill population.

Specifically, we ensured that those beneficiaries who had walked away from the pharmacy for a treatment to help treat their COPD and their asthma now had access to that.

The stakeholders from the provider side were very welcoming to have a payer reaching out to them directly in walking through the alternatives, understanding – and I'll get into this in a little detail in the next slide – but understanding that they're treating a variety of beneficiaries with a multitude of formularies and utilization programs.

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We know that that's a challenge. So having that dialogue we found to be very beneficial, and they were very thankful for that.

The pharmacies were also very willing to help assist contacting the members, in some instances to help them get medication, to remind them that it's available for them.

So we found from that standpoint between the access and the engagement those were all very successful. Now from the challenging side, we saw three things – three groupings, we'll say. Resources, first and foremost, communications and then medication adherence.

So first resources.

While the outreach process was very successful, it was also very resource intensive. You know, the clinician initially doing a retrospective review of reject claims and then looking back individually at each beneficiary's history, we were in the fourth quarter, I believe, at this point in time. So we had quite a bit of history on these. So looking back, to ensure that they had not had access to preferred products for the treatment of that condition.

So that did take some time.

And then probably the most labor intensive piece was the actual contacting of providers – specifically, the physician's office – keeping in mind that we were inserting ourselves into an established process and creating really a new process that didn't exist before. So they weren't really expecting the – or the (pair) to contact (inaudible).

So I think that was new.

They welcomed it. But I don't think they were aware of how to respond to that. So I think there was always that delay. Probably very similar to what maybe a retail pharmacist is experiencing when they try to contact a provider.

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So on average, five to six cases were reviewed a week; and that resulted in about 12 to 15 hours of reviews, phone calls, et cetera, in each of those cases.

Communication, as I already alluded to. Rarely could we get hold of the provider and have an answer on the first call. It usually took more than probably three attempts and then to follow up to give a provider the information, the exchange. And then, actually, communicating that information to the pharmacy and then ensuring that the beneficiary picked it up.

So it was a multi-step, very labor-intensive from that perspective.

And then in the medication adherence. As Tom alluded to, while we were successful in getting the provider to change to a preferred alternative medication, we only saw about a 50-50 – or a 50 percent success in getting the beneficiary to actually go to the pharmacy and pick up the medication.

So I think that was a challenge.

While we were successful in doing that, I think that was something that we did want to look – note as a challenge as well.

So moving on to slide 8.

So operational considerations when considering either a change in policy or expanding the scope of this. First and foremost, education and awareness of the provider formulary alternatives.

You know, I think that's – as we look at these medications, we looked at the pilot. What can we leverage this to do? And we really looked at this as an opportunity to educate the providers in our footprint of our formulary alternatives in the preferred products, and having a dialogue with them also.

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One is we took back some information from them on concerns about our preferred formulary alternatives but also educating them on what they are and having that dialogue.

That was valuable.

Cost effectiveness and sustainability is the next.

As I already alluded to, this is very labor-intensive. To expand the scale of this would be a tremendous load for any PBM or health plan to continue to do this on a large scale.

Finding ways by which the member experiences improve through facilitating the process between the providers, the health plan as well as for the pharmacy is also something that needs to be considered.

So creative ways of leveraging that information.

Fourthly, employing creative solutions to increase the rate of medication pickup and adherence to the prescribed medication regimen.

As I've already noted, our providers – and I don't think we're alone – have multiple formularies from payers and PBMs that they have to know and be aware of.

We want the provider to focus in on treating that patient and getting them the right medication at the right time.

So looking at ways to creatively leverage electronic or technology to get that information to them real-time, such as e-prescribing platforms that dialogue with the PBM or with the health plan to get the formulary and utilization management real time, when they're writing the prescription.

And lastly, plan sponsors engaging pharmacies and providers would create the best opportunity for the beneficiaries to have access to their medications. Specifically, looking into who has the face time with the beneficiary? It is the retail, point of sale pharmacy in most instances.

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Looking at ways to leverage that to enhance and incentivize that relationship at the point of sale is probably the best opportunity to increase access.

One is one of the challenges that we ran into was having the member come back and pick up their medication, having that pharmacist actually have the dialogue with the beneficiary at the time, understanding what's appropriate for them, understanding their history and then communicating that back with the provider and having that relationship there is probably the most beneficial. And it cuts an extra step out of the process that we envision.

So in conclusion as Tom noted, we appreciate the opportunity to have participated in this. We learned a tremendous amount from our standpoint. Some considerations have been taken into as we're beginning to develop our 2017 formularies – particularly around this particular category – and looking at ways to ensure access to our beneficiaries and working with our providers as well moving forward.

Stacey Plizga: All right. Thank you to Tom and Ryan for sharing their pilot program results with us today.

With us here today from Martin's Point Healthcare, we have Jody McDaniel. Jody is the supervisor for Medicare Part D operations.

**Martin's Point Health Care**

*Jody McDaniel – Supervisor, Medicare Part D Operations*

Jody McDaniel: Thank you, Stacey.

I'm on slide 10. Oh, thank you for the invitation to the point of sale pilot and the invitation today—about the pilot.

When we're looking at our case data, the pilot ran from August to December. The total number of cases from October 26 to December 22 of 2015 were 294 cases.

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Of those 294 cases, the number that we were able to approve coverage for through the pilot was 193 cases. And 101 cases were not able to be resolved.

Currently, the plan's outreach to provider, pharmacies and pharmacy help desk is resulting in 66 percent of rejected B versus D claims being resolved at point of sale during this time period.

The resources that were used were supervisor of Part D operations; health benefit advisor; a clinical pharmacist and the manager of strategic programs as well as our PBM clinical advisor – clinical account services; strategic account executive, Health Plan East; director of strategic accounts, Health Plan East, and a clinical pharmacist.

I am now on slide 12: the process. We worked with PBM to pull all prior authorization requests to see what drugs have prior authorization requests and are approved 90 to 100 percent of the time. The outcomes were Ondansetron and Pantoprazole.

The outreach at point of sale from the pharmacist to the pharmacy help desk, the PBM added a rejection message to call the pharmacy help desk with the phone number.

The outcome was the pharmacist can answer a few determining questions to see if the claim should be under B or D for Ondansetron. We also found Ipratropium and Albuterol were identified as high-request approval drugs that could also follow this process.

I am now on slide 13: a case example of the process. A female member received a rejection on December 30.

Our health benefits advisor saw the rejection on a daily report. The health benefits advisor reached out to the pharmacy and provided the pharmacy help desk phone number and questions to expect from the pharmacy help desk.

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The pharmacy contacted the pharmacy help desk and obtained an override on December 31. Our health benefits advisor reached back out to the pharmacy to verify the member picked up the prescription. The member had received her prescription, and no coverage determination was needed.

Lessons learned: slide 14.

Pharmacies and pharmacy help desks were not educated fully in the beginning of this process or our B versus D, causing beneficiaries to still experience issues with point of sale rejections as well as long wait times for pharmacies reaching out to the pharmacy help desk.

We then worked with our PBM strategic account manager to better educate our network pharmacies.

CMS then suggested that we add a process to reach out to the pharmacy's post-paid claim to track if members were picking up these prescriptions. We added this process, and we found we had two outcomes.

Members that received paid claims were picking up their prescriptions. And many times for Ondansetron, members were going through the pharmacy's Healthy Saver program.

This would take our 66 percent of final approved determinations to 49 percent – because the claim was then reversed and fell through the pharmacy's Healthy Saver program.

How does the pilot compare to existing B versus D in coverage determination process?

This is slide 15.

Enhanced communication internally and with member pharmacies and prescribers; more proactive identification and outreach and enhanced and consistent processes and measurement.

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Other ideas slide 16. We identified Glyburide as potential opportunities. CMS has suggested that we use this as our formulary exception drug or – and build a process around point of sale rejections for this drug.

We are currently working with our PBM and conversations have also occurred around Pantoprazole outreach. As this is the other highest prior authorization requests, it is always approved when requested by a beneficiary that is not a non-formulary drug.

Clinical guidance around what outreach would include was supplied to our PBM clinical teams and planned formulary education opportunities with the network provider.

We are now partnering with our preferred pharmacies. Half of our prescriptions go through our preferred pharmacies. We have bi-weekly operation check-in conference calls with preferred pharmacies' account teams to discuss service issues, reject a claim oversight, observing spikes in point of sale rejections for specific drugs – B vs D. flu vaccine, etc. - and providing additional education around the claims processing. Also reaching out to pharmacies on a case-by-case basis to walk them through the process as re-education.

On to slide 18, other potential ways to improve prescriber awareness of formulary products provided guidance to PBM around improved education to network pharmacies and the pharmacy help desk, provided PBM with Glyburide and Pantoprazole clinical alternative and QTY limit discussions with providers from our manager of clinical pharmacy programs.

There's also tracking and trending of prescribing providers an outreach, when appropriate, targeted letter campaigns and targeted outreach calls on high volume providers.

Stacey Plizga: Thank you, Jody, for sharing your case examples and lessons learned with us today.

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Our next speakers from PerformRx include Michelle Juhanson, who is the Director of Compliance and Quality, and Shawn McHale, the Manager of Pharmacy Prior Authorizations.

### **PerformRx, LLC**

*Michelle Juhanson, CHC, CHPC – Director, Compliance & Quality  
Shawn McHale, PharmD – Manager, Pharmacy Prior Authorization*

Michelle Juhanson: Thank you, Stacey.

So just to introduce you to PerformRx and who we are and looking at slide 20, we are a pharmacy benefit manager with just about 5 million lives in 17 states and the District of Columbia.

We've been in the Part D space serving clients since 2006, and we have extensive managed care commercial and employer experience with a focus on health plans that serve the underserved and low income populations.

Our – 60 percent of our 300-plus associates are either licensed clinical pharmacists, pharmacy technicians, prescribers or physicians and/or nurses, and we're proud of our accreditation relationship with URAC, as we're accredited in both pharmacy benefit management and drug therapy management.

And each of these skills sets help to impact the way that we build our program.

So if you turn to slide 21, in terms of what it took to develop our process, it was roughly six weeks from the beginning of the start all the way until we felt like we'd had a very refined program that included feedback from CMS. And the total time investment, for those of you who are interested, is that on per case basis pharmacists spent about 30 minutes.

Technicians spent about 10 minutes per case. From a research and reporting perspective, it was roughly 30 minutes a day. And then from just basic process administration, it took about four hours per week.

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We had 14 individuals from our – from all the various departments that participated. And they included the compliance and quality team who handled the pilot administration and the initial case review; our service delivery team who's accountable for benefits set up and claims processing. They ran the data rejection report to manage the rejection process.

Our prior authorization in medication therapy management teams actually did the case work that Shawn's going to talk about in a moment. And then our formulary and account management teams offered consultative and client engagement support.

So Shawn, tell us a little bit about what drugs we selected.

Shawn McHale: Sure.

We looked at point of sale rejections and coverage determination and redetermination history for a single health plan that dates between June 1, 2015, and August 31, 2015. We identified the most frequently rejected drugs at the point of sale and the most requested drugs at the coverage determination – redetermination level.

Next, we considered PA or step therapy requirements as well as the drug's formulary status. After that, we identified six drugs to begin the pilot with. And later, we added two additional drugs to the scope.

We chose lidocaine five percent patches because the drug's criteria only require that it be used for a specific diagnosis. We felt this would make for a quick and easy interaction with the doctor's office since the doctor would only have to provide us with a diagnosis, and we can go ahead and facilitate an approval.

We added both branded generic Nexium 40-milligram to the list. We noticed pharmacies were writing claims for both brand and generic, and we made it part of our outreach process to determine if brand was actually, truly medically necessary.

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Nexium and Esomeprazole are non-formulary. But the plan has several proton pump inhibitors on formulary for members to try. So we believe through outreaches to the doctor's office, we would be able to discuss the preferred drugs and have the doctor initiate therapy with one of the preferred drugs.

You might also learn from the interaction with the doctor's office that the member has tried and failed a preferred drug, but it is not visible in our claims history.

We chose two high-risk meds – Cyclobenzaprine and Nitrofurantoin. Our (inaudible) department as well as the prior authorization department has experienced making outreaches to the doctor's office to discuss high-risk med utilization and recommending alternative drugs.

Therefore, we believed we would be well-positioned if we included these two drugs.

Patanol eye drops were also included. These drugs required step therapy with a trial of one of two OTC drugs. But doctors might not realize that there were OTC alternatives covered by the plan and might be willing to initiate therapy with the less expensive OTC alternative.

We also believe that members in the plan might have paid out of pocket for these same OTC drugs, not realizing that they were covered by their health plan. Therefore, we wouldn't see them in our claims history if they were purchased.

If this occurred, the doctor would have a record on file and that these OTC meds were prescribed, which could be shared with us.

As we progressed through the pilot, the points of sale rejections were decreased. We chose to add two more drugs to scope – Januvia, which requires step therapy with Metformin – and we knew from the coverage determination level that we issued many approvals for this drug because the member can't tolerate Metformin usage or has some contraindication to the product.

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We believe that we would be readily able to obtain a contraindication of previous trial information during provider outreach.

Nifedipine ER requires step therapy, and much of the decision to add this was claim rejection, volume driven. However, in hindsight, the benefit of adding antihypertensive to the pilot now gave us seven to eight drugs – between Nexium and generic Nexium – drugs used to treat different diagnoses and disease states that were commonly seen in the Medicare population.

Michelle Juhanson: Thanks, Shawn.

So in terms of our process, the goal was to make it as simple as possible because we did have to get multiple departments involved into making this a success. And we wanted extremely limited disruption to the plan and to the beneficiaries.

So Shawn, talk us through the process from the moment that you, at the clinical level, receive the cases.

Shawn McHale: Sure.

Each morning we received a rejection report, which we reviewed. But after that, the process was very similar to our usual customary coverage determination process, with the major exception being that we looped in the dispensing pharmacy into the case review discussions.

We called the pharmacies to confirm the validity of the rejected claim that we saw and, from that call, we learned that many of the rejected claims that we received were really test claims. We then instructed pharmacies to stop submitting un-approvable claims. And while we had them on the phone, we tried to gather any usable information such as a diagnosis that would help us in our case review.

We also told the pharmacies that we were going to contact the doctor's office and that we would follow up with the pharmacies after we initiated some dialogue with the doctor's office.

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We also called the prescriber which is very similar to our usual coverage determination process. We discussed the criteria. We discussed alternative therapy with a preferred agent.

If the drug was not readily approvable right then and there over the phone, we asked the doctor if they would wish to initiate the coverage determination process. So in that sense, it was very similar to the coverage determination.

Michelle Juhanson: Thanks, Shawn.

So from the perspective of the pilot's acceptance going to the next slide, which is number 24 – from a beneficiary protection perspective, we were able to see and support that in 53 percent of our cases. And, we had 19 total that met the pilot criteria.

In 53 percent of the cases, coverage was approved. And in this case, approved means that we were able to ensure that the beneficiary locked out of the pharmacy with a drug that was used to treat their condition regardless of whether or not that was the same drug that was initially rejected.

Conversely, 47 percent of the cases were un-approvable. And that's due largely to the lidocaine cases. Because regardless of our efforts in the pilot process, the beneficiary and their condition was not going to meet the Part D rules for coverage.

And interestingly, we have 68 percent of our cases where the prescribers opted out of the coverage determination process – once they understood what the rules were around coverage.

And then from the perspective of us, you know, from an educational perspective and as an organization, we were really just kind of excited to work with CMS directly and get feedback. And the ability to be creative and flexible – and in an otherwise incredibly regulated and rigid process – and we were happy to be able to show a benefit to both the beneficiaries and

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the health plans that we serve when the pharmacies, as the gentleman from Highmark talked about, were actually aware of and knew our decisions at the end of the day.

So if we move to slide 25, there were some challenges; and I think that we're going to echo some of the things that Ryan and Tom already talked about.

So the process is time- and labor-intensive, with limited automation. Getting clinical information is very difficult for prescribers – especially if it's, you know, after 4:00 on a Friday.

We did have to allot extra time to the pilot participants because the pilot isn't in our staffing model. So we certainly appreciate all the work the individuals at our company did – that did give their extra time and effort.

And the value is really limited in the fourth quarter because there are so few rejections because the health plan members are already quite used to the benefits.

Shawn, would you talk a little bit about some of the programmatic changes we had to make to our prior authorization platform?

Shawn McHale: Sure. We made a mirror image of the health plan in our PerformPA platform, which we called pilot. By doing this, we were able to partition the pilot cases from our coverage determination cases. And we can control or delegate the pilot cases to select members of our staff.

Michelle Juhanson: So one of the questions that CMS asked was, "Well, if this is taking about the same time and energy and effort as a coverage determination, what might be the benefit? Or what – could you see the benefit and value of this process over coverage determinations?"

And at the end of the day, and we're on slide 26, the process is a very nice process to have for plans that can afford to do this. It would boost the number of provider satisfactions.

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There is a huge benefit to letting a pharmacy know – letting pharmacies know – what’s happening. Because you’re going to prevent unnecessary subsequent claim rejections.

We think it’s most beneficial for beneficiaries who are brand new to the health plan of the benefit design. And then, Shawn, from a clinical perspective, what was your – what was your take on what was beneficial?

Shawn McHale: From a clinical perspective, any drug that’s going to prevent a hospitalization and re-hospitalization may benefit from this project.

And also clinically fragile drugs. And by clinically fragile drugs, we mean any drugs that a delay in initiation of its therapy or a break in its therapy would cause a rapid and serious deterioration to the member’s health.

Michelle Juhanson: So the next question we were asked to answer was, “Well, it turns out that when the prescribers do know the formulary rules that they are willing to change.”

So what could the industry do to improve the prescriber awareness? And we’re on slide 27 now.

And so we recommend that CMS and sponsors – and this is particularly something that CMS’s sponsors have a greater ability to do than, for example, pharmacy benefit managers – but investigate programs that increase prescriber accountability to prevent unnecessary point of sale rejections.

At the end of the day, if someone isn’t sent to the pharmacy to get a drug, that that’s the best way to prevent them from having a rejection — that they shouldn’t have to worry about. And there’s ways to do this.

So one could apply greater emphasis on point of care coordination which the Highmark team also brought up, which would lessen the need for a retrospective review.

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We believe that there's already existing regulatory support for this. And we recommend enforcing the adoption of the existing NCPDP formulary benefits 1.0 e-prescribing standards with the prescribers and point-of-care software vendors.

And then for the health plans, you have the ability to monitor rejections at the prescriber level to see and identify places where prescribers are – where there are gaps in formulary knowledge on the prescriber side.

So in summary – and this is our last slide – we really did appreciate the ability to participate in the process. We believe that the program should be voluntary.

We believe that it should be limited to Part D drugs and exclude any demonstration plans.

In terms of the drug, Shawn, your perspective on the final thought?

Shawn McHale: Yes. I think the health plans should be allowed to choose the drugs and the disease states. And I do not think that oral Hep-C and other high-cost specialty drugs should be included.

What we saw during the pilot was that we had in-house a coverage determination request for drugs of this type before we ever saw a rejection at the point of sale.

Michelle Juhanson: And lastly, in terms of the benefit, we do again want to push that this would work well in the transition phase and that pharmacies are critical to the success of the program – and potentially the missing link of the program.

So in summary, we appreciate the opportunity to participate in the pilot. And we look forward to seeing how CMS finalizes this in the call letter.

Stacey Plizga: Thank you, Michelle and Shawn, for sharing your pilot successes and challenges with us today.

Our last speakers that we are going to hear from are from CVS Health.

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We have Carolyn Stang, the Executive Director of Medicare Program Services, and we have Kaitlyn Frank, the Clinical Advisor for Compliance Clinical Operations.

### **CVS Health**

*Kaitlyn Frank, PharmD – Clinical Advisor, Compliance/Clinical Operations*  
*Carolyn Stang, PharmD – Executive Director, Medicare Program Services*

Carolyn Stang: Thank you very much. It is an absolute pleasure to be here.

You're going to be hearing mostly from me.

This is Carolyn. Katie is my backup and my source of all truth and knowledge. So she's here, actually, to keep me very honest.

We also would like to thank CMS for the opportunity to participate in the pilot. I don't know who gets more out of these – CMS or we do – because the dialogues that we are able to have in this sort of a forum are just fabulous.

We challenge them. They challenge us. And at the end of the day, I think everybody's better for it.

So just to introduce you to who CVS Health is – this is on slide 30. We are a pharmacy innovation company who help people on their path to better health. We have 7,800 retail drug stores, nearly 1,000 walk-in medical clinics, have a leading pharmacy benefits manager with more than 70 million plan participants and an expanding specialty services.

We are constantly looking for better ways to deliver optimal health to anyone who comes in contact with CVS.

Specifically within the Medicare realm, we have CVS Medicare Part D services – also known to many of you as CVS Caremark. We are a subsidiary of CVS Health, and we manage relationships with 44 health plan clients for Medicare Part D, with more than 11.6 million Medicare members.

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These relationships also include contracts with both MAPD and PDP health plans using Caremark as their PBM.

In addition, under the auspices of CVS Health, is SilverScript Insurance which is a CVS Health company with more than 5.1 million Part D members. They are members of individual PDP plans or employer group waiver plans.

What I'm going to do – what we did with this is basically focus on the PDP aspect of how a PDP could influence rejects at point of service.

So we pulled together on slide 31 – I want to talk about our very interesting, large cross-functional team.

We included input from our medical affairs folks, clinical operations, SilverScript, our provider engagement team, retail, adjudication and probably others that I am remiss at not mentioning. But they know that they participated and were extremely valuable.

What we did was we brainstormed a number of ideas around improving point of – the point of service experience. Specifically, we looked at three different areas.

The first one was what could we do at point of service? How can we improve our current processes? And then what could we do to impact the initial prescriptions?

And I'm going to focus primarily on the first two.

And starting on slide 32 where we landed.

We did an extensive review of what source of rejects we were seeing with our point of service around primarily prior authorization and various exception rejects.

And we wanted to target drugs that were high-volume, because that was high-disruption.

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We also wanted to target the drugs where the criteria were very clear and succinct, where it was something that could be handled quickly, easily and in the most efficient fashion possible.

So we landed on two thoughts. One was to leverage what many people consider – call smart edits for lack of a better term, which is basically leveraging our adjudication system to be smarter in how it reviews claim history when a claim has been submitted by the pharmacy for adjudication – if there's something that we can do that can handle that transaction in real time at point of service.

So we looked for prior authorization drugs that have very limited approvable diagnoses; and I'll get into the details on that in a moment.

What we ended up selecting, similar to several of the others here, were lidocaine 5 percent patches – good old Lidoderm.

We selected this as our potential point-of-service intervention because there are very limited approvable diagnoses. And what we also found is about 60 percent of all new prescriptions are coming in electronically. So there's a fairly high penetration of electronic prescribing, and a significant number of these had an ICD-10 code already on the claim.

So we wanted to leverage information that was already being passed through, and we had just kind of previously been ignoring.

In one day, we had 185 electronic claims with a diagnosis code for Lidoderm patches. We did not actually execute on this particular item yet. Because it was part of the interesting conversations we had with CMS, there were some potential pitfalls, some things we wanted to clear up. And we wanted to make sure we had no unintended consequences.

And I'll get into that detail later.

The other thing we did look at was proactive outreach for non-formulary drugs very similar to my other colleagues today. And we wanted, again, a drug with clear, simple and a limited number of formulary alternatives. So

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again, similar to many, we actually selected Pantoprazole, a proton pump inhibitor which is non-formulary; and we have three formulary proton pump inhibitors.

On slide 33, we talk a little bit about what we saw. And focusing primarily on the proactive outreach, we looked at three groups.

We had one group where we did a phone call followed by a fax, and actually some we had were fax-phone. We had one intervention group where we did a fax only. And in both of these, what we were trying to do on the fax is get the formulary alternative in front of the prescriber and see if we could get them to either move to that or initiate a full-coverage determination.

We also had a control group. Because we wanted to see if either of these interventions actually improved our success rate over current practice, which is to wait for the prescriber or the member to actually initiate a coverage determination.

We saw a 50 percent improvement over the control group with the combined outreach – with the phone-fax as well as the fax. We didn't see a significant amount of uptick on the phone-fax over the fax only.

Part of that was because we had a very difficult time, actually, getting a hold of a prescriber willing to engage in the conversation. And I'm sure my colleagues here know that they spoke a lot with some of the office staff, many of whom were not willing to make any decision or commitment at that time over the phone. And actually, the majority of them asked us to forward the fax for them, which we did.

But we did get, you know, significant number of positive results. The vast majority were actually moved to a formulary alternative. We actually had only one coverage determination that – or one case that – had a coverage determination where they actually got the Pantoprazole.

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Everything else ended up as a formulary alternative.

We found that the outreach – and given the fact that, you know, in the pilot phase, we didn't automate any of this – this adds a significant amount of time per case. On average, with the phone-fax outreach, it took about an additional 10 ½ minutes per case to do that phone and fax outreach.

Fax only was about nine minutes per case. So the anticipated – the amount of time and effort expended was relatively small. We really wanted to not disrupt current processes to see if there was something we could do that would add benefit.

On slide 34, I want to talk about some of our challenges – and we've all mentioned the difficulty engaging the prescriber office with the phone outreach. We resolved nothing via phone. But we did resolve quite a bit via the fax.

Also within our smart edits – just looking at the lidocaine diagnosis proposal. We were concerned about the fact that since this is occurring at point of service, it is not a full coverage determination process, that the approval – if it is an approvable diagnosis – is really only good for the life of that current prescription.

So if a different doctor wrote for a new prescription or changed the diagnosis code that they submitted, it would end up rejecting; and a full coverage determination would be required. And we were a little concerned about how are we going to manage that with the enrollees to not cause confusion?

On slide 35, I want to go back to the three pathways we considered initially. We thought there was a lot of benefit to this. And we are continuing to explore it further.

We do believe that the most impactful interventions need to occur as close to point of prescribing as humanly possible. Because that was the only way you're going to prevent the reject of point of service.

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However, we did find that with our proactive outreach, that we actually were getting our enrollees on appropriate formulary alternatives – which is a big

advantage for them as they will be significantly less out-of-pocket costs than even if they had gotten an improved formulary exemption.

So what can be done at point of service? We are still exploring the smart edits.

We think there's still opportunity to leverage e-prescribing on the ICD-10 codes that are included on a prescription. And we are going to be having continuing dialogue with CMS to see, you know, what we can do to possibly try this once we get past the welcome season.

This is not a good time of year to try something new.

In terms of how we can improve our current process, based on our experience with this very small, non-formulary proactive outreach program that was done for the pilot, we've actually expanded into a limited proof of concept trial during transition fill.

We're in the height of transition fill season. We are looking at claims that got a transition fill and are doing similar outreach to prescriber offices to see if we can resolve that before the next claim comes, and there actually is a rejected point of service.

The goal is to take advantage of this time frame to improve the experience for the enrollee.

Early results of our limited outreach have been promising and are very similar to what we saw with the non-formulary outreach that we have. And we will be doing similar outcomes assessments, including comparing to a control group to see if we actually have a real uptick with this other process.

But what did we do to impact the initial prescription? We do believe that the most impactful way to reduce the rejects at point of service is to impact how they're written, whether it is providing formulary alternatives via the

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e-prescribing platforms which were also mentioned by several of my colleagues here as well as leveraging electronic prior authorization to actually deal with those coverage determinations that need to go through and getting those done, actually, before the script is written. So when they go, it is approved already.

Thank you very much.

### **Questions & Answers Session**

*Stacey Plizga – Moderator, Provider Resources, Inc.  
All Speakers*

Stacey Plizga: OK. Thank you, Carolyn, and Kaitlyn for supporting Carolyn today. We will now accept questions and comments from participants on the phone.

Because of time constraints, we are limiting all callers to one question. And we ask that you state your name and your organization. And also please identify the speaker or organization that your question is directed toward.

Remember, if you would like to ask a question, please press star 1. And over to you, Christie.

Operator: Thank you. One moment for the first question.

And your first question is from Yanna Polson.

Yanna Polson: Yes. Hello. I am from LA Care, which is a big public health plan in Los Angeles, and my question is for Tom and Ryan.

On slide 6, I'm interested in your finding that only 50 percent of the patients who were switched to an alternate medication actually picked up their prescription. And I was wondering if you looked to see if those 50 percent who did not pick up the authorized prescription actually ended up on the original medication that they wanted in the first place or if you have any other ideas why 50 percent of the patients didn't pick up their medications.

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And also, would you consider a control group in this kind of a study to see if you did not do the intervention, what number of patients would actually pick up their prescription. Thank you.

Ryan Cox: Sure. This is Ryan. Thank you for the questions.

And I'm going to start at the last question and move backwards. That's how my brain works. So bear with me.

So with regard to having a control group, I think as we've looked back at this and the scientist in me says, "Yes. We probably should have done a control group, but we did not."

We were – so, you know, best practices and what I've heard today particularly from some of my colleagues in the room, I think it would have been beneficial to see if there was a difference? We did not measure a difference between our standard, which is basically wait for the request to come in as opposed to the outreach.

OK?

With regard to the 50 percent that we saw that did not obtain it, I would say there was a variety of reasons that we saw.

In some instances, the member found out what the copay was going to be for the medication the physician switched them to and were concerned about the cost associated with that.

In instances where we were going from basically switching them to an Advair or Symbicort, they were concerned with the coinsurance or copay associated with those products. I know that was some of the feedback.

The others were that the patient wanted to talk, or the member wanted to talk with their provider further before making that and had never – and then basically through the pilot program, we did not see them obtain a paid claim through the pharmacy, unfortunately.

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So those would be probably the most common that we saw. Others, there's some challenges in reaching beneficiaries. You may not have an access phone. We would do outreach via the mail – the old-fashioned way of saying, "We're trying to reach you," and hope for them to call us back.

But those I think would be the most – the common reasons for that.

Anything else, Tom?

Tom Boettler: (Inaudible).

Stacey Plizga: Next question, please.

Operator: Your next question is from Luke Harrison.

Luke Harrison: Hi. My name's Luke Harrison from Blue Cross of Idaho. I have a question for PerformRx.

Stacey Plizga: Luke, could you please speak up? We cannot hear you.

Luke Harrison: Oh, sure. Is this better?

Stacey Plizga: Little bit.

Luke Harrison: OK. I'm calling from Blue Cross of Idaho. My question is for PerformRx.

One of the medications you selected was Patanol eye drops. You selected that because members may buy that over the counter, and you may not have claims history for that.

Covering your POS process, you don't indicate outreach to providers to see if they actually filled those over the counter eye drops. I was wondering where the – if there was any sort of member intervention for that one included in the process.

Shawn McHale: Hi, Luke, and thank you for your question. This is Shawn speaking.

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In our coverage determination process, there is member intervention. We are going to call the member to find out if they would have tried one of those medications. But since member contact I believe is out of the scope of the pilot project, we did not contact the member during the pilot.

We did contact the doctor, however, to try and ascertain that information.

Stacey Plizga: Christie, we're ready for the next question, please.

Operator: Your next question is from Stacy Sanders.

Stacy Sanders: Hi. This is Stacy Sanders at the Medicare Rights Center. Thanks so much for this presentation. It's been very informative.

My question is for Highmark and PerformRx. I think in both of your presentations you mentioned a sort of time commitment and the labor that was a part of this outreach process after rejection.

I'm wondering if you can speak to how that compares to the time commitment and staffing that's involved with prescriber outreach in the traditional coverage determination process.

So is there more or less time spent in this outreach process versus any outreach that occurs when a beneficiary does, in fact, request a coverage determination?

Shawn McHale: Hi, Stacy, and thank you for your question. This is Shawn from PerformRx.

We found that the time commitment was very similar to the time commitment for the coverage determination process. However, in the pilot project we did not have to adhere to the 24- or 72-hour turnaround times.

Because we had a larger space to work in, we may have made one or two or even sometimes three official outreaches. So in that sense, committing the time, the effort put into the outreaches would have been a little bit longer than the coverage information process.

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Ryan Cox: And this is Ryan from Highmark. I would concur with Shawn as well that time spent compared to a traditional coverage determination was similar. But given the lack of a clock ticking, so to speak, we expanded what we did to try to really advocate on behalf of the beneficiary in these instances.

So, you know, looking at what the intention of the pilot program was to do, I think we did commit a lot more resources to this just to ensure that.

Stacy Sanders: Great. Thank you.

Operator: And again, as a reminder, to ask a question press star 1.

We have no further questions at this time.

Stacey Plizga: OK. We do have a question here.

Tom Boettler: Hi. This is Tom Boettler from Highmark. And this, Shawn, is directed towards you, Shawn, and Michelle from PerformRx.

One of the things that we struggled with was understanding whether these were test claims coming through. So interested to hear from you guys as to how you identified those. What was the volume? And then how did you work with the pharmacies to sort of change that?

Michelle Juhanson: It was interesting.

All right, Tom. This is Michelle. And so in the cases that we had, the total numbers of test claims – 13 percent of the total cases that we had were test claims.

And the only way that we were able to figure it out was actually calling the pharmacies and asking, “Did you really intend to prescribe this medication?”

For the lidocaine’s, there were a couple of cases where the beneficiary asked for lidocaine. They had a relative who was a nurse, and they wanted to see how much it would cost.

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And in general, we're seeing that pharmacies either want to see how much something's going to cost or whether or not a claim is going to reject. And they may do a lot of typing and squiggling and putting numbers in just to see what claim is going to pay.

So in our small, limited case, it was 13 percent of the total.

Stacey Plizga: We're ready for the next question.

Operator: Your next question is from Chris Bowers.

Chris Bowers: Yes, hi. This is Chris Bowers with United Healthcare.

My question, I guess, is really either for Highmark or Martin's Point. Depending on – I'm not sure if this is applicable but if you guys do manage, you know, MAPD plans with a medical component, I wonder was there – was there any thought to or exploration of using medical claims data to obtain information to either respond to point of sale rejects or even in certain cases, you know, proactively prevent them?

Jody McDaniel: Hi. Thank you for the question. This is Jody with Martin's Point.

Our future work is to partner with our Medicare – our medical claims department to discuss proactive outreach for those drugs.

Ryan Cox: And this is Ryan from Highmark. I think as we were going about this and we were focusing primarily on non-formulary rejections for COPD and asthma drugs, we didn't anticipate that there would be a tremendous amount of non-medically accepted use of these products that we didn't leverage, in this instance our medical data for this offer to go pilot. Chris, thank you.

Stacey Plizga: We're ready for the next question.

Operator: Your next question is from Jessica Tice.

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Jessica Tice: Hi. This is Jessica Tice with Anthem, and I'm – sorry if I missed it. But I was curious to know the time frame between when you saw the reject to when you were reaching out to the prescriber's office.

Was it the same day or next day?

Stacey Plizga: Who is your question directed towards, please?

Jessica Tice: Anyone, I guess. Anyone that was making calls to prescribers based on drug rejects.

Ryan Cox: So I have the microphone in my face, Jessica. So this is Ryan from Highmark.

So we would retrospectively look back on a weekly basis. So we could be a week out, or we could be three days out.

I would look to my other colleagues in the room.

Ryan Cox: OK. So we're looking – everybody was daily except for us. We were retrospective up to a week, and everybody else was doing a daily process.

Michelle Juhanson: We did exclude weekends.

Sorry. So this is Michelle. Just to echo. We were daily. But we excluded weekends, because doctors aren't open on the weekends.

So on average, it took about 5.38 days for our cases to resolve from the date of the rejection to the date that we confirm with the pharmacy that a drug was picked up or the prescriber opted out of the process.

Stacey Plizga: OK. We're ready for the next question.

Operator: Your next question is from Sheila Neiman.

Sheila Neiman: Hold on. Hold on.

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Yes, this question is directed to Highmark or anybody else who would care to answer.

I was wondering, what is an effective way to increase formulary awareness with the physicians? Electronically, if they're going to go on with every plan that they have contacted with, there are a lot of different formularies that they have to be aware of.

So what is a practical solution to have formulary awareness heightened?

Ryan Cox: One of the items that we looked at – and this is Ryan. Everybody knows my voice, I think.

So one of the things that we looked at was leveraging – and I believe my colleagues also addressed this as opportunities as well – is enforcement of the use of e-prescribing tools and utilizing the information that's on there that would have the formulary information associated with that particular beneficiary.

We acknowledge the fact – particularly in our footprint, and I don't think there are many that are participating as the only plan in a particular region where they're going to have multiple formularies and utilization measurements. Even in some instances within a plan, you may have some differences as well.

We do acknowledge and want to recognize (that) the providers – we want them to focus on the care of the beneficiary first and foremost. But there are tools at their disposal that are real time electronically, and leveraging that technology to get that information to them real time when they're prescribing with a message back that this is not a formulary drug. Or this is a non-preferred product that may have a higher cost share for your patient.

I think it would really be the best opportunities in those instances.

Sheila Neiman: Thank you.

Stacey Plizga: We're ready for the next question.

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Operator: Your next question is from Russ Dillard.

Russ Dillard: Hi. This is Russ Dillard, United Healthcare. A question, really, for any or all presenters.

As I look at the presentations, it's sort of hard to determine if the meeting turnaround time from point of sale reject to that of coverage determination approval or denial was improved or significantly improved from the pilot when compared to that of your current coverage determination processes.

I think that might be the truest measure of success with this pilot. Can anyone elaborate or estimate on those turnaround times?

Carolyn Stang: Hi. This is Carolyn Stang with CVS Health.

What we found was actually the opposite of what you would think. Within our control group, we had the shortest turnaround time from reject to coverage determination request. And we believe that's actually because these were the most motivated individuals to get the coverage determination resolved.

It actually took longer to get from the reject to an appropriate resolution with the proactive outreach. On the other hand, we had more successes. As I mentioned earlier, we had a 50 percent uptick over our control group with the proactive outreach.

So it may have taken longer, but more people got on appropriate therapy. It's a tradeoff.

Michelle Juhanson: And...

Operator: You're next...

Michelle Juhanson: This is Michelle from PerformRX. I did want to note that to your question, I don't know that there's necessarily a one-to-one match. Because the purpose of the pilot from our perspective and that we understood was to identify the people who slip through the cracks.

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So we're talking about people where their prescribers are not actually actively going to go through the coverage determination process.

And in the case of our pilot, we just assumed that they weren't going to go through the coverage determination process.

So again, on average, our cases took about 5.38 days from rejection all the way to a complete resolution. But what we don't know in the real world is the actual amount of time that prescribers wait between the point of sale rejection and actually submitting the coverage determination.

So I think Shawn was saying to me from his scientific point of view that our sample size is too small to tell.

Stacey Plizga: We're ready for the next question.

Operator: Your next question is from Kimberly Vivalve.

Kimberly Vivalve: Yes. I was wondering how important do folks feel about the availability of the 24-hour help desk.

So I saw that was a good part of the Martin's Point Healthcare interventions. And I was wondering aside from, say, (B versus D), which we address daily already (in) our plan, I'm curious if we – if we didn't have that ability for the pharmacy to get a – get a response going on a 24-hour basis from a help desk, would that – do you feel that would have hindered your response rate?

It was my impression that those – these were getting addressed, like, on the spot. Is that – is that an accurate representation? Or was there some delay where pharmacy staff actually got to looking at the interaction with the pharmacy the next day?

I'm trying to wrap my head around that.

Carolyn Stang: This is Carolyn Stang, because we're actually the PBM that supports Martin's Point.

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And so I can probably address some of the things with the pharmacy help desk.

What Martin's Point was doing was specifically looking at the B versus D determinations where the determination can be made by information readily available at the pharmacy.

The pharmacy help desk is a readily available source for getting that back and forth dialogue. And the pharmacy help desk can also approve the override immediately for Part D.

So this was an ideal opportunity to leverage that asset to get as close to real time determination as we could. And again, it's because there's – they're there when the pharmacists are there.

Jody McDaniel: Hi. And this is Jody. So what we were doing is taking the prescriber office out of the equation.

So the rejection happened at the pharmacy – they reached out to the pharmacy help desk, answered a couple of questions, and the claim was resolved at that time.

Kimberly Vivalve: OK. Now that – now I'm following that story a little better. I appreciate that very much.

Thank you. Thank you both.

Stacey Plizga: OK. Next question, please.

Operator: Your next question is from Cathy Gibson.

Cathy Gibson: Hi. This is Cathy Gibson from Anthem. And my only question was related to G&A and complaints – grievance and appeals and complaints.

Does anyone – did any of these pilots evaluate? Was there any improvement that they saw in grievance and appeals and complaints with numbers?

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Carolyn Stang: Well, we did not specifically look at this – and this is Carolyn from CVS Health.

We really wouldn't have expected any. Keep in mind these were very small proof of concept trials, and I think everyone in the room will agree that none of them involved enough interventions for us to – even to – if we even saw one, would it have been relevant or a meaningful uptick?

So again, it's a great idea, and it's something that I think we will all monitor going forward. But because of the tiny size of these pilots, I don't think we would have had meaningful information.

Cathy Gibson: OK. Thank you.

Operator: And as a reminder to ask a question, press star 1. Your next question is from Dalissa Kelly.

Dalissa Kelly: Hi. This is Dalissa Kelly from Blue Cross Blue Shield of Massachusetts. This question is regarding the B versus D pilot program. When are these B versus D requests considered coverage – the true coverage determinations? Or are they more like payment decisions that are made at the pharmacy help desk?

Just curious to see how you track the coverage determination piece and documentation required for an actual case and the turnaround.

Stacey Plizga: Is that directed toward anyone in particular?

Dalissa Kelly: Yes, please.

Just anybody that can answer the question.

Stacey Plizga: Can you submit the question to the POS Pilot mailbox for questions? So we can get a better answer for you?

And that is [pospilot@cms.hhs.gov](mailto:pospilot@cms.hhs.gov).

Dalissa Kelly: Sure.

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Stacey Plizga: OK. At this time, I would like to thank everyone for their questions today. In closing things out for us, we have Dr. Jeff Kelman, who is calling in. And he is the Medical Officer for the Center for Medicare.

### **Closing Remarks**

*Dr. Jeff Kelman – Medical Officer, Center for Medicare*

Jeffrey Kelman: Thank you, Stacey. Thank you, Beckie.

First of all, I would like to repeat how appreciative we all are to our plan collaborators for their efforts in this project.

I'm going to try to briefly summarize some of the findings. It's very difficult, of course, to summarize a project as inventive, with as much potential as this one.

However, I think we can define at least four themes from the project and certain questions for the future.

First of all and most important, this effort demonstrates the incredible potential for testing new flexible pilot programs in the Part D space – through cooperation with our high quality plans.

In certain ways, this is the most important product from this pilot, as it allows for future projects to help us continuously improve Part D and potentially Part C down the road.

I've learned over the past 10 years that policy ideas always benefit from on-the-ground experience in the real world. And so the quote from Winston Churchill – “This is not the end, not even the beginning of the end. But it is, perhaps, the beginning – the end of the beginning.”

We gratefully look forward to continuing these kinds of interactions going forward.

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Now pragmatically returning to the pilot, first of all, there's the universe of possible non-adjudicated drugs which were successfully defined as two very different approaches.

In the presentations as well as some discussions we've had with our plan sponsors, we've seen multiple creative drug lists.

First of all, drugs with the highest rate of original denials and point of service – either because of a lack of formulary presence or PA requirements.

Next, drugs with the highest rate of eventual approval during CD processes – coverage determination processes – either formulary exceptions or PA fulfillment.

Then there are the drugs with the lowest rates of approval but the highest rates of alternative prescriptions being adjudicated.

These are often drugs with either high generic penetration in the sub-class or very mature brand penetration in the sub-class.

And last is B versus D drugs with very simple standard PA requirements – for example, transplant drugs for Medicare-approved transplants.

All of these are legitimate approaches, and they might be combined to produce even greater specificity and sensitivity.

Next, how do we find success in this pilot? There are really two measures which you've heard.

One is alternate drugs approved and dispensed without a CD. And the second is requested drugs approved and dispensed without a CD.

In general looking at the data, I think it's safe to conclude that all approaches yielded an approval rate greater than 50 percent – sometimes significantly so, although with a lower file dispensing rate which, itself, is instructive in the end.

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There were two specific problems which won't be surprising to anybody in this business that were brought to light repeatedly. One, the scalability of the current approaches may be limited by the increase in time and labor costs, which may turn out to be greater than savings from reduced coverage determinations.

And the second, as in the standard CD process, the rate limiting factor was prescriber engagement. Anyone who has gone through an audit will appreciate this point all too readily.

So what are the questions for the future based on this project?

There are a lot of them. To define a few, first of all drug identification. Can we define an improved set of drugs that are so efficiently resolved through these palliative processes that they are scalable?

The second: prevention. Can we reduce denials at point of sale upstream through either physical physician education on specific formularies or the development and use of electronic prescribing with formulary and PA standards?

The latter seems to have the greatest potential to preempt denial.

Next is point of service action through pharmacists. This, by the way, was a repeated theme. And the question really is can contracted pharmacies be engaged to outreach to prescribers directly at time with the first presentation of the prescription and service a facilitator between the plan and the prescriber to use formulary alternatives to fill PAs in real time?

The next is active surveillance. Are there – and this is something we've touched on but not fully developed, and it might be in the future. Are there data mining approaches that will identify high denial rate drugs that can lead to either prescriber-specific education – for example, there may be prescribers who don't understand that a atorvastatin really is Lipitor – or change their formulary status? Eliminate PAs if always fulfilled.

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The nice thing about active surveillance is it can be – lead to an ongoing change in processes even during plan year.

I think there is real potential in answering of all these questions.

Once again, we'd like to thank you all for your incredible efforts and are optimistic and intend to engage you all in the future.

Thank you.

### **Audio Closing**

*Stacey Plizga – Moderator, Provider Resources, Inc.*

Stacey Plizga: Thank you, Dr. Kelman.

All right. I would just like to remind everyone that if you have additional comments or questions about the pilot that were not addressed during this call today, you may send them to the mailbox [pospilot@cms.hhs.gov](mailto:pospilot@cms.hhs.gov). And also, CMS expects to provide additional information about the pilot in the 2017 call letter.

And finally, we would just like to thank everyone for your participation today. And have a wonderful evening.

Thank you.

Operator: Thank you. This does conclude today's conference call. You may now disconnect.

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