

## TRANSCRIPT

### Day 1 02: Improving Drug Utilization

*Tudor, Thorp, Wirth*

I'm so pleased to be here. As Tim told you this morning, we've been active in responding to a public health crisis related to pharmaceutical overdoses. Opioid overdose, as he said this morning, is the second leading cause of unintentional death in the United States. And this comes after motor vehicle crashes. We've been working with the Office of the National Council on Drug Policy on a number of efforts, both across CMS and across the government. We've been working with the other agencies – including FDA, CDC, SAMSA, and a number of Department of Defense agencies.

In these meetings there's a lot of serious work. But in the last one, there was lots of concern about whether it is acceptable that Lady GaGa's site is getting more hits about her anti-drug abuse prevention than it is that the government gets hits. So that's the level of understanding some of these people have.

We found that there are a number of questionable instances of access to opioids in the Medicare Part D Program, including multiple prescribers who are not aware of each other. Beginning first with an HPMS Memo to you in September of 2011, followed by additional development in December of that year, and then new and advanced approaches in the 2013 Draft and final Call Letters, CMS has been working on an approach to help Plans identify and manage the most egregious cases of opioid overutilization.

This summer we conducted a pilot and worked effectively with three different Part D Plans who piloted this approach in different ways. I'm not going to steal their thunder to talk about what they found, but I want to thank each and every one of them. And we have representatives of those pilot Plans here. I'd like to introduce to you the participants – over here, Jennifer Webber from Humana; David Martin at the end of the table from United; and Carolyn Stang from SilverScript. I'd like to give them a thank you for this and a hand.

I'd like also to introduce Lisa Thorpe and Gary Wirth of my staff. And they're going to take this over and talk about both the HPMS Memo that went out on Friday and the Morphine Equivalent Dose Analysis that we did and included in the package you should have gotten on Friday afternoon. Thank you, and I'll turn it over to Lisa.

Thank you. So this is just a quick session overview of the background and then what we're here to talk about today – Improved Retrospective DUR Programming and Case Management, the Morphine Equivalent Dose Analysis, and then the pilot panel and some questions.

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So here's the background of what we're talking about today. Dr. Tudor alluded to some of this. And I don't want to read it to you, but here are some pretty startling statistics about opioid overutilization in the United States. Most importantly, I would refer to the GAO Report there in the last bullet where questionable instances of access to opioids was found in the Part D program.

And as Dr. Tudor alluded to, we've been working on an approach since the fall to help sponsors identify and manage the most concerning cases of opioid overutilization in the Part D program. And what I'm going to do here is provide the regulatory framework for what we're going to talk about with the panelists with Dr. Tudor moderating. So the approach kind of culminated in the final Call Letter in April of 2012. And in the Call Letter, and it's under this title – Improved Retrospective DUR Programming in Case Management – we set out three levels that Part D Sponsors should use to better manage opioid use in their Plans. There are sort of three levels that were discussed in the final Call Letter. The first two have to do with better formulary management to stop potential opioid overutilization at the pharmacy counter. And I encourage everyone to go back and read the final Call Letter. There's a lot of detail about those two "levels," as we call them – Level One and Level Two. They talk about safety controls at point of sale. They talk about quantity limits at point of sale, and things that Part D Sponsors can already do to better engage in formulary management.

The Level Three that we spoke of in the Call Letter is this Retrospective DUR Programming in Case Management. And in June of this year, we put out in draft particularly sample letters that go along with the case management. We put out draft guidance on this Level for sponsors. And then, as Dr. Tudor said, we finalized it this past Friday in an HPMS Memo after taking into account the comments that we received from all of you, which we thank you very much for.

So in the Draft Guidance and in now the Final Guidance that went out Friday, there is much more detail about the components that CMS expects to see in this retrospective case management to look at those cases that aren't going to be caught at the pharmacy counter. And it also, as I said, provides Sample Letters to engage in case management with prescribers and also notify beneficiaries of any actions taking that would limit their current access to opioids.

So what is the case management? Part D Sponsors should look for apparent duplicative opioid drug use over sustained periods of time or across multiple opioid drug products in high doses. These are the cases CMS expects Part D Sponsors to focus on. The focus, again, is on high dosage, sustained opioid use, and multiple providers. And Gary is going to share in just a few minutes the targeting methodology that CMS has shared with Sponsors in the Final Memo that went out Friday that can help you effectively target the cases that you should be looking at. So it should not be an overwhelming number of the beneficiaries in your Plans.

So once you've identified these cases, what CMS expects you to do is to have clinical staff communicate with prescribers and beneficiaries to ascertain whether the use is medically necessary. As part of this communication, you should give the prescribers information about the existence of multiple prescribers because that's what we're talking about here – likely prescribers who don't know about each other – and the beneficiary's total opioid utilization. As part of this communication, you're expected to have a result from the case management, which is to determine that the current use of the beneficiary is medically necessary, appropriate, and safe. The case management may determine that a lower level is what's needed because there are multiple

prescribers, and they didn't know that they were all prescribing opioids. Or the third result may be there's no opioids needed. But that's something that clinical staff at the Plans will have to determine as part of the case management and reaching out to prescribers.

So we have here on the slide, "No status quo if prescribers are non-responsive." And in addition to the case management aspect that CMS expects you to engage in, this is probably the most novel thing for Part D Sponsors, which is something has to be done about opioid overutilization and it can't be an acceptable response that if prescribers are non-responsive that the utilization continues. So Part D Sponsors will have to determine in those cases what to do with P&T Committee involvement.

There are different things you can do at a beneficiary level at point of sale – perhaps a prior off on all future opioid prescriptions for a beneficiary where the prescribers are not responding, perhaps lowering the dose that they're able to get over time, if that seems warranted – that's kind of up to the Sponsors to figure out. But we just want to be clear that non-responsiveness is not a reason to not take action.

And then there may be some cases, as we learned in the pilot, that may look like medic referrals are appropriate. Again, that's for Part D Sponsors to determine. So in those cases where it's determined that the current level of opioid use by the beneficiary is not appropriate and the Sponsor is going to implement a beneficiary level claim edit to prevent an unsafe dosage from being covered by the Part D Program, you are expected to send a 30-day advance notice to the beneficiary telling them of this – that this edit will be in place. And of course the beneficiary has a right to contest that decision. Again, the Sample Letters that are provided in the Final Guidance that went out on Friday, there is a sample for giving this notice to beneficiaries. And the samples are not required. These are suggested Sample Letters. They really are Sample Letters; and they can be adapted by Sponsors, as they see fit, for their own programs.

And then the last thing that I would mention is there's no lock in to specific prescribers or pharmacies. That's not allowed in the Part D Program. And the beneficiary level edit that needs to be put in place has to be related to the amount of opioids that they can receive -- not to the prescribers that are writing the prescriptions, nor to the pharmacies that are dispensing them.

And so now I'm going to turn it over to Gary to talk about the targeting methodology that I think you'll find very interesting.

Thanks, Lisa.

As we engaged in this process to develop the case management approach, we were concerned about finding an effective tool that we could use and you could use to assess the potential risks of overutilization of opioids in the Part D Program. As most of you know in the room, this has been very difficult in the past because FDA has not assigned maximum doses to opioid drugs. We also know, though, that these products are often compared to morphine. Based upon their analgesia, what is their equivalence to morphine?

So we looked at the literature and found studies that associated the cumulative morphine equivalent dose of all the opioid products with the potential risk for adverse effects and overdose. We also found that in the state of Washington, they've implemented public policy based upon morphine equivalent dose to help protect the patients and reduce risk of overdose and death from overutilization of opioids.

So we thought, "Can we apply this methodology to Part D?" So we undertook this task. In the process you have on your screen there, we looked at Part D data from 2011. And the challenge for this was we were looking at claims data. Most of the conversion tables look at just an individual opioid. But we had to find a methodology to work with claims data, which is what you will have to use as well.

The first step was to identify what are the exclusion conditions – what conditions do we not want to automatically include in an opioid abusive study? And we selected cancer and hospice. That's also supported in the literature. We developed a morphine equivalent that is a conversion table for the opioid analgesics, which were mostly oral. There were also some non-injectables, such as fentanyl, for which you had to adjust the standard conversion tables. There were several very smart pharmacists from CMS who worked together to make this methodology work and to adjust the conversion tables as needed to fit claims data.

We then calculated the cumulative daily morphine equivalent dose for each beneficiary and then assessed various levels of morphine equivalent dose to identify how much opioids were being used in Part D and how much are high risk. We also looked at the number of days they were taking the opioids, both separately and consecutive days, as well as other criteria that are very typically used, such as doctor shopping and pharmacy shopping and those kind of things.

In the end, we concluded that, yes, there is a very effective tool to assess and manage the risks associated with the use of opioids. Here are the results of our study, again using 2011 PDE data. After excluding cancer and hospice care, nearly nine million Part D beneficiaries used an opioid analgesic in 2011. Almost two million exceeded what we are considering the threshold of 120mg morphine equivalent dose per day for at least one day. 1.8 million beneficiaries is a huge number, and not really workable for you or for us to evaluate. We further looked at how long they were taking the morphine equivalent dose and identified that 225,000 beneficiaries exceeded the 120mg threshold for at least 90 consecutive days. We think this is a good target population. These are the ones that are potentially at risk for overutilization of opioids.

However, we also wanted to consider the other factors. So we looked at the number of pharmacies, the number of physicians – felt that anything more than three prescribers and three pharmacies were important levels. So we calculated how many of the beneficiaries were taking more than the threshold for 90 consecutive days as well as going to more than three or more pharmacies and identified 222,000. In our mind this is a very reasonable, narrow targeted population that Part D Sponsors can use for the initial implementation of a case management approach. And we think you could clearly use our methodology or other methodology to identify such a narrow, useful, and reasonable target as you implement the Case Management Program.

With that, I'm going to give you the panel discussion. These are the folks you've all been waiting to hear from because they worked on it so diligently with us.

Thanks, Gary. We want to turn this over to the panel really now, but I'll help facilitate this. We want to first start talking about the targeting criteria. When we started this, we didn't have this fully developed – the targeting criteria – so the Plans were sort of on their own though we helped guide them to some of the Washington state work that had been done in the area. So I'd like to have you all comment on what your targeting criteria were and how you selected the beneficiaries.

We used a variety of targeting criteria including multiple prescribers, multiple pharmacies. We looked at number of claims rather than morphine equivalent dose as well as concurrency of prescribers' claims, number of opioids, and pulled all of that together and kind of created a total risk score. We did subsequently look at the morphine equivalent doses of the nine cases that we targeted for review in the pilot and found that the MEDs ranged from actually 35, which was an extreme doctor shopper going to emergency rooms two or three times a week, up to 3600mg morphine equivalent dose – which made us all cringe.

At Humana, we also utilized multiple pharmacies – so we did three or more pharmacies, three or more prescribers, and actually utilized nine or more claims. And to Carolyn's point, we also looked at MED; but we didn't incorporate that as part of our targeting criteria at the time. But we did look at the range pre-intervention and post-interventions to see if there's a decrease not only in doctor shopping and pharmacy shopping but as well as decreasing the morphine equivalent dose. And we utilized mainly for this pilot, we utilized MAPD population and utilized ICD-9 codes to exclude the cancer patients as well, and then provided our physicians with a letter of patient report with 30 days' worth of claims.

We used essentially the same approach. In addition, we tried to get some diversity. So we chose people based on age, sex, and type of product they had.

The pilot plans were given the authority to use whatever they wanted. All we asked was that they met with us, either on a weekly or bi-weekly basis, to talk about what they were doing, what they were finding. And so I'd like to move now into sort of what the due diligence was around the cases they identified. So who would like to go first?

That was actually probably the most interesting part of this for us in that no two cases were alike. Similar, we looked for a diverse group of individuals to target for the pilot just so that we could get some experience. But we came across some interesting challenges. The first challenge was actually identifying who the prescribers were we should actually go out and communicate with. We did send written communications to all prescribers. But when you've got a slurry of emergency department docs, we had some prescribers that told us they had discharged the patient from their practice, so that led to some interesting challenges, up and to a couple of them that the prescribers simply vanished without a trace. So that was also a very interesting challenge for us.

What we did though find that once we did kind of identify who we needed to target, we thought about that targeting a bit broadly – so it wasn't always just the prescribers of the opioids. But in some of the cases where most of that prescribing was being done by emergency departments, we

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looked at who actually seemed to be the primary care or the primary practitioner for the individual. This took time, and I think that was probably our biggest learning from the due diligence – is it was multiple outreaches, and it took a little bit longer than we anticipated.

The same as what Carolyn has shared, our biggest challenges were due diligence is that we noticed that mainly – we contacted actually all the providers that coincided with the members. And the ER physicians were probably the most challenging ones because they shared with us, “Well, we’re ER doctors. We don’t see chronic patients. Contact their PCP.” But a lot of times, the members that we identified did not have primary care providers. So our pharmacists that were doing these consultations looked to see, to Carolyn’s point, which provider was more of their chronic medication patients. So they really emphasized that.

Additionally, even though we couldn't get ahold of the ER physicians, the patient report that we provided to them – all the nurses, the sectors that we spoke with, actually said, “That was helpful. Put that in the chart for future use.” And interestingly, some of our cases where the patient actually had a pain contract with the providers, they didn’t realize the pain contract was being breached until they saw our letter and our patient report. So that was a very interesting finding on our end.

I found that the physician extenders were a bit fearful in speaking with me. However, when I was able to get through to a doc, they all talked to me. I reached out to 36 providers and had conversations with 8 of them. So that’s kind of a hit rate of 22%. Perhaps a better way to look at it though is that of the five cases under consideration, we resolved four of them, or 80%, with these conversations.

I think CMS was the only one that had the privilege of listening to each of these pilot Plans talk independently. So we were able to take different kinds of lessons from what was happening. Some Plans – and it may have been a result of how they targeted the cases that they were looking at – some Plans had a lot of intervention with physicians. And I think that United is one of those. I think other Plans had a little more difficulty. It may have been because they were getting lots of ER cases. And so the Plans were left, if you will, with different kinds of cases that came out of the pilot.

I would like to say that all the Plans only had about six weeks to do this, from the time that we got them to participate and they were seemingly willing – I don't know, you never know what a letter from me means – but they seemed to want to do it. So anyway, they participated willingly; and we gave them a very short time, and they still were willing to do this.

So I'd like to move to any more comments you have about your outreach to prescribers and beneficiaries. I think one of the things that came as part of the pilot was that we eliminated the requirement to alert the beneficiary that this was going on. And that came directly out of some of the experiences that the pilot Plans had.

Yes, I will reiterate that. We found that the initial Inquiry Letter was a bit distressing to the beneficiary, so we were very pleased to see that that was eliminated in the latest Memo. Other than that though, the physicians were remarkably cooperative. Once we could identify the primary prescriber who was willing to kind of be the care coordinator for the individual beneficiary, they welcomed the conversions with our physicians. And really it was a very collaborative experience.

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We were very pleased that it was received as well as it was. That really I think was our biggest takeaway.

We did have a few physicians that weren't exactly thrilled to hear from us at the beginning. But once they found that we were actually trying to help them manage what probably was a very challenging patient for them, they welcomed our calls and were extremely cooperative.

So for our outreach providers, we identified about 27 provider members. And we had about 50% where we actually did get ahold of the prescribers. And based on that, to Carolyn's point, many were receptive. They were actually thankful that we were doing this outreach to them. And interestingly, one of the providers actually found out the prescription that supposedly she wrote was actually forged. So she really was interested in learning more about the program itself, as well as some of the other providers also wanted to know about the morphine equivalent dose. So our pharmacists did have an opportunity to speak to the providers with, "Look at that daily MED," and for them to utilize for their future patients.

And as for the members, we actually had a pretty good success rate. Out of the five that we targeted, we did speak to four of them. And the one that we didn't speak to, he actually was the one that was utilizing the forged prescription. But needless to say, when we looked at the pre- and post-intervention with the letter itself, it did decrease the doctor shopping and the morphine equivalent dose.

I agree. Our members we found were stressed and distressed at the initial contact. The day after the project started, I actually got a call out of the blue from one of the members saying, "I know it looks bad, but my identity was stolen. And all these prescriptions are being cashed by other people." So I naturally raised that when I talked to the treating physicians, and they doubted the veracity of that. That was the case, however, also where the three physicians sort of got together and agreed that the patient should be managed with a single agent at a certain quantity limit, and it was a good resolution to that case.

Thank you. So the next is to talk about the outcomes and follow up – exactly how many of these resulted in a beneficiary-specific edit, no matter what that was.

As I mentioned, we looked at nine cases. We have sent out five beneficiary and prescriber notifications of a beneficiary-specific utilization edit, most of which are quantity limits or we will only cover very specific drugs in very specific quantities. We have two cases that are still pending. We had two cases where we really were not able to either find a primary physician because this person only sees the emergency room docs, and another one which was just a very challenging case with an uncooperative physician. So we are doing an external evaluation to determine medical necessity.

So, seven out of our nine will end up with some sort of a utilization edit. The other two were felt to be medically necessary, and we were able to close the case. We have sent the letters. As I mentioned, we have sent five of the seven potential letters. We have had one inquiry back from a beneficiary, which we think will result in an Exception Request probably in the next day or so. But

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at this point, it's been too soon for us to see any really measureable change. And since the letters just went out a week or two ago, we feel it's still a little bit early.

So on our end, we actually did not put any service edits for the beneficiary. Out of the five members, two providers said, "I am seeing this patient, and I'm going to be weaning off this medication." So two of the five, we didn't have to have any type of intervention. And the one that we could not get ahold of, interestingly enough, we could only get ahold of his prescribers as well. And he was also (inaudible), he's the one that had the forged prescriptions multiple times at a pharmacy where our pharmacist did reach out to one of the managers at one of the pharmacies. And he said, "Yes, this prescription looks forged." And a week ago we did catch him bringing in a forged prescription as well. So this member, we are having difficulty reaching the providers for that case.

And then the other member, it was interesting. We found out that her son was utilizing the member's medications. So we really discussed and emphasized with the patient, "If you do get a pain medication, make sure you let the pharmacist and pharmacies know to put it on file. So only fill it when you really do need the medication." And based on that, just looking at our preliminary post-intervention analyses based on prescription claims and looking at doctors and pharmacy providers, and that number did decrease.

And then the last patient we did not utilize beneficiary edit either. And this person, she started seeing only one provider as soon as we discussed points of – I mean, granted we know that we can't restrict the doctors or one provider/one pharmacy. But for all them we really emphasized with the patients on the phone stating, "You really want to do fill at one pharmacy because of their health concern – not only possibly over dosage, but drug to drug interactions." So utilizing that approach was very receiving on that end.

Yes, we resolved four of our five cases. Again, as I mentioned just previously, one of them was by consensus among the treating physicians. I'm struck that some cases that appear very egregious on the surface are not so when you delve into the details of the case. And super therapeutic doses appears to be good medicine in some cases, and that was true in two of these. Another case resulted in a referral to a university pain center. And the final case is yet unresolved was someone seeing multiple doctors in multiple emergency rooms. We could not resolve things at the level of the physician. And I found it not very fruitful to be talking to emergency room doctors who were not charged with the longitudinal care of the patient. That case is still open and is being worked by our internal investigation unit.

So you can see a broad variety of instances that happen – different kinds of patients, different kinds of interventions, different kinds of responses from physicians. So moving to lessons learned?

I would say the first lesson we learned is that when CMS asks you to pilot something, jump up and down and say, "Yes, yes, pick me, pick me!" This was an amazing experience for us in that it allowed us to kind of verify that we were going down the right path to begin with and has allowed us to partner with CMS on tweaking our process so that we really think we've got something that will be a best-in-class practice starting the first of the year.

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Besides that, other things that we learned is that things seemed to take longer than we thought they might. It took quite a bit of due diligence to reach all the appropriate prescribers. And many of the prescriber calls were multiple calls – the first one to kind of discuss the case. Many of our prescribers wanted to meet with their patient before they discussed a potential utilization protocol. We found that the complete medication profile was extremely welcomed by the prescribers. This was very often an eye opener and what they found was an extremely useful piece of information.

And probably the biggest lesson we learned was the necessity for thinking broadly around your internal organization and preparing them for this. It was not simply our Drug Utilization Review Team. But we needed to engage, and very successfully engaged, our Customer Service Team, our Grievance Team, so that they knew about these unique patients or members that may be calling in about the letters. We engaged our Coverage Determination and Redetermination Team so that they would understand if they got an Exception Request from one of these beneficiaries that there was a great deal of history behind it. We very much engaged our Medical Directors and just about anybody, right down to cornering people in the hallway and saying, “Hey, you want to hear about this really cool thing we’re doing?” We found that that paid off. Great internal communication I think was probably one of the biggest lessons we learned that is going to be essential for the success of this program.

So to Carolyn’s point, yes, I think this pilot was a very good experience for Humana as well. It helps us think ahead what needs to be implemented first quarter of 2013. With that said, just even targeting our beneficiaries for this – we are right now currently working with one of our departments building a tracker – a database – to utilizing the morphine equivalent dose and combining that with the three prescribers and three pharmacies Gary had mentioned earlier. And in addition to that, we’re also looking at ways to – oh, for the morphine equivalent dose, one of the things that three states that do have Tramadol as controlled force substances, we actually included that doing some research. There are various conversion rates between morphine to Tramadol. And so we also incorporated that in for the three states that do have that as a controlled substance. So that’s another additional research we had to do to create the morphine equivalent dose database.

And another thing we learned is because Humana is based out of Kentucky, we actually had one of the patient reports had Tramadol and one of the physicians got upset because the state that he was practicing in, Tramadol was not considered a controlled substance. So that’s going to be our due diligence on our end. But on the prescriber letter side, we do want to incorporate in the letter stating these three states – Kentucky, Tennessee, and Arkansas – Tramadol is considered a controlled force substance and also referring them to the Washington State Opiate Guidelines and pointing them to the website for the MED calculation. It’s fairly easy to utilize. It’s pretty quick. As long as you know what they’re taking, it does provide that information for them.

To Carolyn’s point, we did a lot of working with our various departments. It took quite a bit longer than what we thought as well. We had to go through some of our communication pieces to be reviewed internally as well to make sure that those seemed sound. But granted, we did utilize the sample that CMS provided which helped greatly. But we know some of the things that we do want to incorporate for 2013.

And another thing for lessons learned is trying to figure out ways to engage providers to help us with – one of the things that we struggled with on our outcomes was providers saying, “Oh, thank you for informing. I will no longer see this patient. We’re going to discharge them.” That’s one of the barriers that we really faced. So that’s one of our tenets -- that we’re going to work to figure out how we could engage these providers in the future.

Yeah, I was struck at how many lessons you could take away from really a small, qualitative study like this. A couple of the docs were really bending my ear, and I was taking copious notes. I hope I captured most of what they had to say. The main lessons I took away, again, were looking at the surface of a case doesn't really tell you enough because what can appear egregious may not be at all. It really doesn't pay to be talking to docs that aren't the PCPs taking longitudinal care of the patients. This type of case management that we attempted is quite resource intensive. We had 34 staff involved, and it took me quite a bit of time to have these conversations with the various docs.

Many of the physicians had access to State databases that track drug use. And I was struck that these databases weren't used. I think they could have helped in this case. So it's pretty clear that they're not integrated into the workflow of the physicians, and we have to be more proactive and get the information out in front of the doctors – not require that they go looking for the information.

Some of them were pretty intrigued by the idea of morphine equivalent doses. They felt that it would be helpful if they knew proactively when patients were getting up on the higher scales of this. So I'm wondering – we're getting more and more sophisticated every year in analyzing claims data and messaging to physicians about quality opportunities – I'm wondering if we might also do that in morphine equivalent doses and sort of get to the problem at earlier levels than Level Three that we're devoting our discussions to today.

Behavioral health concerns seem to be significant. And I think care management needs to leverage those resources. And again, in the GAO Report that sparked a lot of this discussion, they found a couple of drugs that were gateway drugs, if you will, to addiction. And those drugs were well represented in these small numbers of patients also. So I think that health plans need to address the desirability of allowing these gateway drugs, if you will, to be used.

Thank you. I think CMS's lesson obviously from this is the value of these pilots, the value of working with the Plans and hearing what they were doing, and letting them do whatever approach they wanted to because I think we drastically changed what we put out in June from what we ended up being finalized.