STATE OF CALIFORNIA
DEPARTMENT OF INDUSTRIAL RELATIONS
DIVISION OF WORKERS' COMPENSATION

PUBLIC HEARING

MONDAY, MAY 1, 2017
Elihu Harris State Office Building Auditorium
1515 Clay Street
Oakland, California

George Parisotto, JD
Moderator
Acting Administrative Director

Raymond Meister, MD
Medical Director

Jacqueline Schauer, JD
Industrial Relations Counsel

Maureen Gray
Regulations Coordinator

DIR Official Reporters: Emily Hatton and Rex Holt

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(Time Noted: 10:04 AM)

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Good morning and Happy May Day. My name is George Parisotto, and I'm the Acting Administrative Director of the Division of Workers' Compensation. This is our noticed public hearing for the proposed Medical Treatment Utilization Schedule Formulary Regulations.

There are copies of proposed regulations on our front desk, which you will see over here on my stage right. I think I said that right. I don't know how it is from your perspective over there. Please make sure you sign the sign-in sheet and indicate if you want to testify today.

I'd like to introduce the other members of the Division who are joining me. On my left is Jackie Schauer, Industrial Relations Counsel, and on my right is Dr. Raymond Meister, the DWC Executive Medical Director. We're also joined by Maureen Gray, our Regulations Coordinator, and our Hearing Reporters today, which are Rex Holt and Emily Hatton, if I've got that right.

When you come up, I'd like you to please give your card, if you have a card, to Maureen. All testimony today will be taken down by our hearing reporters. If you have any written testimony that you would like to give to us right now, please give it to Maureen. If you wish to be notified of the final adoption of our formulary or subsequent changes, please provide

your complete name and mailing address on our hearing registration attendance sheet, which is located at the sign-in table. The final notice and notice of changes to the regulations will be sent to everybody who requests that information.

I will call the names for those who have checked that they wanted to testify. At the end of the list -- when I get to the end of everybody's name, I'll check to see if anybody new has come in who wants to testify or if anybody else has additional comments. This hearing will continue as long as there are people who want to testify on our regulations, but we'll close at 5 o'clock this afternoon. If the hearing continues into the lunch hour, we will take at least an hour break. So please maybe you will plan on that. Written comments, if you do have them, can be given to Maureen, as I said, right now or will be accepted by fax, email, or hand delivery up to 5 o'clock this afternoon at the Division's office, and that's located on the 18th floor of this building. You have to cross the security, go up the elevator to the 18th floor. Please give them to our receptionist.

The purpose of this hearing is to receive comments on our proposed formulary, and we welcome any comments you have about them. We will not question, respond, or discuss anyone's comments, although we may ask for clarification or ask you to elaborate on any points you are presenting. All comments, both

given today orally or provided in writing, will be considered in determining whether we will make any revisions to our regulations. When you come up, please restrict the comments -- the subject of your comments to the regulations and any suggestions you have for changing them. Also we ask that you please limit your comments to three minutes.

Since this is May 1st and we are in Oakland, the possibility that May Day celebrations, demonstrations, and/or rallies may occur in the area, whether it be at Frank Ogawa Plaza or here at the Federal Building, which is a block down. I sincerely doubt they will involve people with flowers in their hair, dancing around a pole. These incidences could impact traffic, the availability of public transportation, or caffeine options. I don't expect any issues at this hearing. Please check your mobile devices -- I know you all have them -- for any news and updates.

Now again, a reminder, please make sure you've signed in and, if you wish to speak, that you have checked the boxes indicating so. When you come up, please give your card to Maureen -- your business card to Maureen if you have them so we can get the correct spelling of your name in the transcript. Please speak into our microphone, which is, again, here to my right which is at the podium. Before beginning your comments, please state your name and identify yourself for the record.

So let me go to our list, and our first person is Denise

Algire.

DENISE ALGIRE: Algire.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Algire. Sorry. I do apologize in advance for mispronunciations of names, which I am very well known for.

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DENISE ALGIRE

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Good morning. I'm Denise Algire with Albertson's companies and we are also members of CCWC and we will be providing written comments. I just wanted to include a few more details or provide a little bit more commentary.

First of all, I'd like to commend the DWC on putting together the formulary based on evidence-based medicine and tied to evidence. We feel like that's critically important. So we really want to commend the DWC for doing that.

Specifically though I'd like to call your attention to the area called Perioperative Fill in the formulary. We feel like this needs to be further defined to avoid unintended consequences. We feel like it needs to be further defined to eliminate zero day -- postoperative days. I'm not sure if you're aware the CMA defines global days in three different areas: Zero-to-eight postoperative period, a ten-day postoperative period, and then a 90-day postoperative period. We feel that including zero-day postoperative periods could

have unintended consequences and include simple procedures where you wouldn't normally have a postoperative period, and those are my comments.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

DENISE ALGIRE: Thank you.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: I hope I can get this one right. Brian Allen.

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BRIAN ALLEN

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Thank you. Good morning. I'll be brief. We did submit written comments and so a lot of this will be in our written comments. I just wanted to kind of reiterate a couple points.

First of all, we would like to thank the Division for the process. We think it was a very open process. We think it was a very inclusive process, and I think the outcome was very good. We're very appreciative about it. We do have a couple suggestions.

The first one that I want to kind of emphasize is the definition section. We think the definition of compound should be strengthened a little bit to avoid any potential loopholes. We suggested some language in our written comments. I know that it would be hard for you to believe that someone could actually exploit a loophole in the system, but we think it's better to tighten this up before they get exposed by

exploitation.

The other thing we have some concern about is the transition of existing claimants who are using non-preferred drugs. The rule talks about a transition time, but there is no definitive time frame.

And the other part of it that was concerning to us is that it talks about the claims adjuster not being able to unilaterally make decisions or change treatment, but there is nothing in there that puts any kind of onus or burden on the treating providers to actually implement a transition plan. So we suggest, in our written comments, just to move that line. It would be difficult and challenging if you put the claims adjusters in the untenable position of having to try to transition somebody and have someone on the other end of the treating side and not even have a conversation about that. The way the rules are written, you're sort of at a stalemate at that point and nothing has changed. I think it would be important to put some kind of language in there just to sort of encourage those conversations to occur.

The other area that we have some concern about was the -- just the overall effective date. We talked with some of our customers and trading partners. There is some concern that they may not be ready programmatically just because of the tight window. So we recommended in our written comments that you change your approach to the legislature about pushing that

effective date out a little bit and give everybody more time.

I think the other important thing about that is that one of the hallmarks of success in other states adopting a formulary is there was an educational process that happened by the state to providers and that occurred over a period of several months. With this tight time frame when this rule is finalized and the effective date, there would not be a whole lot of time to do that education process, and we think that's an important component. It's not mentioned anywhere in the rule. It's certainly something that could be done, just to help medical providers and those who are treating injured workers and working for injured workers to understand what does this formulary do and how should we implement this for maximum effectiveness. I think that's a really important component and something that we've seen drive success for formularies in other states.

So we recommend that, if you can get that delay, do that education process, I think your results long-term -- while they will be delayed a little bit, you'll have better results and fewer disputes that occur because of the formulary. I think other than that, those are kind of the main points.

Like I said, I think it's a very good proposed draft with a couple minor tweaks that we would recommender, and we're happy to help answer any questions you might have, and if you need additional inside work, we're open to that as well. Thank

you very much.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Don Lipsy.

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DON LIPSY

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Don Lipsy, First Script Network Services. I feel like I have the easiest job, following Brian. We have very similar comments as both being parts of PBM. I will say my outlook is a little bit more out of the negative side than Brian's, not from lack of effort from anyone who took part in any part of the process.

We have significant concerns, as a PBM and also as someone who works closely with the networks in the State of California from the prescribers' side, about the two pieces that were echoed just a few minutes ago. First of all, the close adoptive date of July 1st really, at this point in time, seems untenable from both a programmatic, as well as an educational, perspective. I think, if you look at the language -- and we will suggest these as well in written form -- there is wiggle room to take an approach that says this is the format, these are the standards that are being adopted, but delay the effective date to actually match up with what is out there, from a utilization review perspective, new rules that come through the pipe on 1-1-2018. That six-month time frame seems

to be in line with what other states have done and substantial enough to allow for, not only, the transitional process for the injured worker, which is the person we should be valuing most, but also to reach out to prescribers.

It's a little bit funny when I look at the opioid guidelines from last year and everything. There was this great educational process that we had where we had this info, and prescribers were trained for that. There is a bit of a fallacy that we've seen play out in other states that have been exploring formularies that people really delay actually getting on board with the program, so to speak, until about the last quarter of development.

So, again, delay time allows PBMs, networks, everyone else to catch up from a programing perspective and also allows folks a really more important part of the transitioning of injured workers to a safer plan and working with those problematic prescribers. That is really kind of one of the reasons we have a formulary in the first place, from a legislative perspective.

The other part that I would push for -- and I have spoken with folks from ACOEM. Having the level of specificity of the formulary today, as what's been posted, is okay. It's kind of like looking at drugs from a high school gymnasium perspective. It's not quite the draw as looking at it from a major league baseball stadium. But what we see in other states that is very effective is a more NDC-driven formulary. Of course, as a PBM,

we can program to that, but when we're talking about making life easier for everyone, including the injured worker and the prescriber and anyone in the administrative process, including the State at the end of the day, it's a much better system if we actually use a more specific NDC-driven formulary. ACOEM has commented and hopefully -- I know Carlos is here today -- that someone from that group will support this as well. They can program, as other states have done, to a more specific level, making things accessible to everyone within the work comp system at very little to no cost. That seems to then level the playing field so we don't have that uncertainty, something that will drive better communication, better conversation, better treatment or outcome, which I think is really what everyone is looking for. So that --

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Ben Roberts.

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BEN ROBERTS

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Thanks for the opportunity to speak this morning on the formulary and the proposed rules. I represent PRIUM. My name is Ben Roberts.

PRIUM is a utilization review organization in the State of California. We've been operating since 2009 and have acute focus nationally on the overuse and misuse of prescription

drugs. As a result, we've been involved in formulary implementations across the country, and we are pleased with the steps that California has taken with proposed rules. I think they represent an excellent draft at addressing all the majors of concern that -- the major areas of concern that we feel are important and should be looked at when considering adopting the formulary.

We submitted some very specific written comments on the language of the rules, tweaks to specific wording, as well as definitions, and I just want to comment broadly on two specific areas publicly while I have an opportunity, the first just being around the transition period.

As others have stated, the transition period is an important component of the formulary, transitioning injured workers who are already on non-preferred medications, injured workers who are maybe on long-term opioids, things that require a significant clinical and administrative process. We need a discontinuing transition to an appropriate medication regimen. It concerns PRIUM that there is no definition around "phase in." The use of the term "phase in" is used in the rules, but there is no guidance there: Phased in over what period of time; who's responsible for enforcing, kind of, the process; who's responsible for educating the physicians and the other stakeholders. So we have some concerns about that language.

The other issue that I want to just mention briefly is

around the perspective of the new requirement. The Rand Report -- quoting from the Rand Report that DWC relied on in order to, I suppose, come up with maybe these rules -- specifically says, "[a]n initial transition may be less important for California [Workers' Compensation] program because the MTUS has been in effect since 2004, and [utilization review] typically occurs for all prescriptions on a prospective basis."

As a utilization review organization, we do not see that as the case. We don't feel that prescription drugs are routinely requested through prospective review process through the submission of the RFA process. So we have some concerns about the assumption that physicians will follow the requirement to prospectively request utilization review on non-preferred drugs and other scenarios outlined in the rules. If the burden is on the physicians to request prospective review and they weren't adequately educated and they haven't been given the guidance that that's what they are going to need to do going forward, we don't see on July 1st any significant change in behavior of physicians; and we're going to see essentially what the payers are doing today, which is filling medications, even if they are non-preferred, and then having to use the retrospective review process to effectively deny those medications going forward. PRIUM doesn't feel that meets the ultimate goal of the formulary, which is to reduce the

administrative burden and the associated administrative cost of the formulary. So we would like those things addressed specifically in a future draft as indicated in our written comments as well. Thank you.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Don Schinske.

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DON SCHINSKE

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Good morning. I'm Don Schinske. I'm here today on behalf of Western Occupational and Environmental Medical Association. We've submitted full comments, but I just want to highlight a couple of things.

For starters, we agree with the DWC's choice to derive a formulary based on the ACOEM guidelines published by the Reed Group. We, of course, are the regional component of ACOEM so we're on the same family tree but fundamentally we agree that evidence-based is a good place to build a formulary from and it's a good place to turn first as drugs and treatments evolve.

Three points really -- one, we do have some concerns about the fulfillment of prescriptions at the pharmacy level for drugs that are either preferred or non-preferred. Depending on the diagnosis, denials that are based on retroactive review/retrospective review could create confusion at the pharmacy and lead to uncertainty about what exactly gets

reimbursed and what doesn't, and could undermine the whole enterprise. We don't have a solution but we do see a problem.

Secondly, we do think there are some specific medications, which we've listed in our comments, that could be added to the preferred list. These include antivirals for exposures to blood-borne pathogens. They include antibiotics for soft-tissue infections. There are some others. We think they all are safe and unlikely to be abused and are appropriate.

Finally is the issue of legacy prescriptions for what we now believe are non-preferred drugs. We believe that any weaning or changes to the drug regimen should be instituted by the payer rather than the physician. I think that will help make things very clear where the focus of the first action lies. There needs to be some sort of robust consultation process between the physician and the adjuster or the UR doc or the PBM as things apply. It needs to start with some sort of shared understanding that it may take a year or two to transition patients that have complex pain management regimes. Thank you.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Diane Worley.

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DIANE WORLEY

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Good morning. I'm Diane Worley with the California Applicants' Attorneys Association. Thank you for the opportunity to have us here today to provide testimony, as well as submit written comments.

I want to echo the comments that came before from everyone about the amount of work that I understand went into preparing this draft, all the meetings you've held. I have great respect and appreciate the work you've done. Our written comments will be submitted later on today. I provided a copy to Maureen, but I want to highlight two areas of concern that we have with the proposed formulary as drafted.

First is with regard to the transition provisions which other stakeholders have mentioned. AB 1124 requires a phased implementation of the formulary for those workers who are in the system before July 1st of this year, and in the current draft, I don't see any phase implementation. There is a lot of discussion about other formularies in other states, such as Texas where they had a two-year implementation transition for so-called legacy workers.

There are a couple of important things about that. One, it gives doctors a time frame to do something, to do -- a protocol to transition workers onto formulary medications or to

justify why they need to stay on medications that they've been on for years.

The second, and even more important, aspect of having a time frame is to protect the workers. You have a fine line you're walking here with this formulary, which has a lot of policy benefits, saving costs to the system, and decreasing opioid dependency. For those workers, through no fault of their own, who are already caught up in that problem, it really is completely necessary to protect them during the implementation period.

The second part of that is that, in the draft, it talks about the claims administrators can't, I think, abruptly terminate medication. Well, claims administrators cannot deny or delay treatment as it is already in the system. They are not supposed to. That's supposed to go to UR so they can't do that.

What I can perceive happening, based on some of the problems occurring going on with UR and IMR, is that when a new prescription comes in for that existing medication and it's a non-formulary drug or a non-preferred drug, that's going to go to UR and get denied based on MTUS's formulary, and that's going to create a lot of problems for the workers. So to be in compliance with AB 1124, I think you need to put back into the draft a phase implementation for workers before July 1st.

The last thing is with regard to the preferred drug list.

The term evidence-based medicine is kind of thrown around loosely and we all understand it to mean medical recommendations that are tied into treatment guidelines or scientific studies or literature. I think the preferred drug list is something where drugs were selected based on their low cost, and obviously there are no opioids on that list. I understand the policy consideration there obviously, but I don't think we should talk about the preferred drug list as being evidence-based. It's above my pay grade to talk about what medications to be added to the preferred drug list so I leave that to the physicians and pharmacists to say that. I do think there must be a number of other drugs that can be on that list and not increase the current problems we're having with opioids.

And the last part of that is with regard to UR and IMR. I'm a little skeptical that we're going to see a lot of change in cost benefits in the system from a reduction in UR and IMR for pharmaceuticals if you just look at the preferred drug list, because most of those drugs shouldn't be going through UR anyway. We're talking about aspirin, Tylenol, Pepcid. If those things are going through UR on an isolated basis, we're really in trouble. I'm hoping that they aren't, but the counterpoint to that means you're not going to see a lot of cost savings if that's the intention with the preferred drug list. Thank you.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Matthew O'Shea.

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MATTHEW O'SHEA

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Good morning. Thank you. I'm Matt O'Shea with Safeway, Albertsons, and I appreciate all the work and effort that you guys did in drafting the regulation.

I did have one comment, and that is in terms of the physician dispensing section, which is 9792.27.8. Within that section, you left an exclusion for the MPNs, which we appreciate, where there's an MPN contract that restricts physician dispensing, but you did not include anything for the Pharmacy Benefit Networks. And the concern is that 9792.27.1, physician dispense definition, is so far distance from this section that someone's going to look at this section and say, "I can prescribe medication."

There's no exclusion for the Pharmacy Benefit Network, and we're going to create a lot of liens and other issues that we're going to have to litigate. So I think it's a very simple solution to add a section excluding the Pharmacy Benefit Networks under 4600.2(a).

That's my comment. Thank you.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Saul Allweiss.

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SAUL ALLWEISS

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Hi, my name is Saul Allweiss. I'm an attorney. I'm here actually testifying on behalf of Schools Insurance Authority. SIA is part of CCWC and will be submitting written comments, but there is one particular section I would like to highlight a major concern over, and I'm referring to 9792.23.3(b).

This is the paragraph that addresses transition, and there's one sentence that we believe must be stricken from the regulations. It's towards the middle. It states, "The claims administrator shall not unilaterally terminate or deny previously approved treatment," and this is in regard to injuries prior to 7-1-17.

The problem here is that there's nothing in the formulary that ever allows for the claims administrator to unilaterally deny a medication. All the formulary does is if it's a preferred medication, it gets filled. If it's non-preferred, it goes to pre-authorization. So with there being absolutely no provision anywhere in the formulary for a claims administrator to unilaterally deny anything, by putting this sentence in there, it's going to cause a firestorm of litigation.

I believe advocates for the other side of my profession will be immediately jumping on that to say that even if a

claims administrator did a utilization review for an injury prior to 7-1-17, that the claims administrator can't cut off that medication because there is -- because of this sentence taken out of context. So I foresee a tremendous amount of litigation and suing. And while I'm confident that we'll prevail in the courts eventually, probably millions of dollars of resources will be expended fighting that battle, and I really believe that this one sentence should be taken out.

There are other technical comments that CCWC has offered that I will defer to the written comments. And like others have mentioned, I want to recognize the herculean effort that the administration's done, Dr. Meister and Administrative Director Parisotto in getting these regs out. We appreciate it, and thank you for letting me testify.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Mark Pew.

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MARK PEW

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Good morning. My name is Mark Pew with PRIUM. My colleague Ben Roberts already represented the comments that we've publicly posted in regards that I have really only one comment, and it's been reiterated already before that July 1st is a premature implementation date.

From the way I've read AB 1124, there's two phrases that

the legislature guessed two years ago that might be appropriate from a timing standpoint. They said to establish a drug formulary on or before July 1st, it shall include a drug formulary. I believe that language allows you to establish the drug formulary, the rules, and finalize the rules that allows you flexibility to decide when it should be implemented.

I've lived through formularies in a variety of other states. There's a lot of moving parts. There's a lot of stakeholders engaged in this. I've often made the comment that a bad formulary is worse than no formulary at all. I would adjust that a little bit and say a premature formulary is worse than no formulary at all.

So I would recommend that you delay the implementation date to potentially January 1st which should allow everyone enough time. From my understanding in talking with folks, a lot of folks have not begun the implementation or the design phase or the programming phase until the rules have been finalized. And at this juncture, we're just shy of two months to the implementation date. So my recommendation would be to move the implementation date when it is actually effective to be January 1st instead of July 1st.

Thank you very much.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Roman Kownacki.

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ROMAN KOWNACKI

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Good morning. My name is Roman Kownacki. I'm the Medical Director for Kaiser Permanente's Occupational Health Program. I'm going to start with my conclusion and recommendation first.

My feeling is that it will increase some of the frictional costs in the system that I know this was trying to eliminate. There is room for inconsistency in the application, and there's a fundamental flaw in just the current design. And while I appreciate linking evidence-based medicine into it, there is a fundamental problem that I think needs to be addressed.

The spirit of this is really to control bad behavior and ideally not impact good behavior or even reward good behavior, and this really extends -- we've talked a lot about physician prescribing, but it also extends to UR companies. And the plan to have some medications that are non-preferred, but then they could be recommended or non-recommended by ACOEM guidelines is a fundamental flaw in this, and I'll take -- I'll use the example of Cyclobenzaprine.

Cyclobenzaprine, according to ACOEM, can be used for severe neck pain, or it will be inappropriate for mild neck pain. That really is going to be on the basis of the subject of experience of pain by that patient to determine whether it's recommended or non-recommended. Okay. But it's a

non-preferred drug to begin with; so you'll have to go through the preapproval process. Fundamentally, that's a very, very difficult process to manage.

Number two, our back of the envelope calculation for our organization is that conservatively, about 50 percent of our prescriptions would now have to require an RFA, and when we see 64,000 new injuries per year, that equated to about 30,000 prescriptions that would now have to go through the RFA process. That really is going to be challenging not only for us, but also -- I'll go back to you're trying to not -- you're trying to get rid of bad behavior, and that bad behavior that occurs in a small fraction of physicians is the same bad behavior that occurs on the UR side on that small group of UR companies too.

So my recommendation would be as to push the date out, get it right, get it right the first time, and that way we won't be here a year later trying to solve the problems that are created by some of the fundamental problems with the way it's currently written.

Thank you.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Kim Ehrlich.

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KIM EHRLICH

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Thank you, and good morning. My name is Kim Ehrlich. I'm with Express Scripts, and really, the comments that I have to make are not anything that you haven't already heard, but I just feel that we need to go on record and state these verbally for everyone.

I think we all would agree that we really need and want this formulary to work, and so with that said, we just have a couple of recommendations or considerations we'd like you to give some thorough thought to.

The first is the effective date and, you know, while the effective date -- adoption date can remain the same, we feel strongly that with less than 60 days at this point that it would be appropriate to move the implementation date to 1-1-18. As we all know, there's a lot of time and effort that goes into it, and without the rules being finalized -- the regulations being finalized at this point, I think it would be helpful for all system participants to have that opportunity to not only do systematic changes if necessary, but also process changes within the system. And this all for, you know, the betterment of the stakeholders and success of the formulary.

Second would be the transition time, and I think we would all agree that whether it's personal work, we all work against

deadlines. And without a deadline in there, I think that we're not going to see the discussions that need to take place between all the system participants to transition or agree to a treatment plan that's appropriate for the betterment of the injured worker.

And so that's really all I had to say today. Appreciate it. Thank you.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Mitch Seaman.

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MITCH SEAMAN

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Mitch Seaman with the California Labor Federation. I thank you for the opportunity to come in and testify today. We'll be submitting written comments this afternoon; so we just wanted to kind of generally expand on a few points that we're going to make in that letter and also add to some of the comments that have already been said.

The one that -- the one issue that we wanted to raise respective to the specific language was that we think it would be helpful to clarify that for preferred drugs, not only is prospective review not required, but that it's really not allowed. That the intent here is to take a lot of the unnecessary costs out of the system with prospective or with unnecessary URs. And that while it's pretty clear to a lot of

people that read this that, "Oh, that means you shouldn't do prospective UR for drugs that are on the preferred list," it could be less clear to others.

When you say something is, you know, not allowed, that's a lot more -- something is prohibited. It's a lot more clear than it is not required prior to dispensing. And so, you know, it seems like it could be read either way. We don't see any harm in just including language in there that would clarify for those preferred drugs, prospective review is not allowed.

We would also echo comments that have been made about potential confusion over the word "unilaterally" and that sentence. You know, we very much appreciate the intent of that sentence and overall appreciate a lot of the changes made in the second draft that responded to a lot of the concerns raised by us and other stakeholders in the system and do think that that's a step in the right direction to say that we need to be careful in kicking workers off of their old treatment plan as this new formulary takes place, but the specific wording of that sentence could create a lot of confusion and potentially litigation. And so, hopefully, there's a future draft that clarifies the intent without raising that risk of additional litigation.

And then just generally wanted to make the comment that this is a pretty restrictive formulary. From the worker's perspective, it's a little concerning just overall. I mean,

obviously, we didn't hear a lot of concerns from our members, like, "Hey, make it harder for me to get drugs. That's how you fix this system." We hear the exact opposite all the time. And so, just putting this into place, especially one that is as restrictive as this, is kind of a giant leap of faith on the part of injured workers that we can get this right and that we can make this work without a real negative impact on injured workers that are in a really tough place trying to get these drugs that they need to feel better.

And so with that in mind, we hope that a future draft of the language can expand the study that's outlined in the current version to really get into what the effectiveness is on workers and make sure that once this is in effect and being implemented, that there isn't some new struggle workers are facing. That there isn't just this, you know, sort of ripple effect across the system where workers can't get the drugs they need because physicians are afraid it's going to be denied, or they don't want to deal with UR, or the, you know, the UR process for non-preferred drugs is for some reason not working, that those does exist in other states. It is kind of new here, and I assume the other state's language doesn't look exactly like ours.

So there is a real concern here that workers could suffer no matter how hard we try to get this right. So we do think it's really, really important to expand that study and make

sure that there aren't those negative impacts -- or if there are, then we can identify them and deal with them as quickly as possible.

We also think that it would be good to expand that study and make sure that as it was just raised by one of the speakers, requiring UR for non-preferred drugs isn't doing a lot to increase costs that, you know, we finally got costs moving in the right direction at kind of a predictable rate, and requiring UR on a lot of the drugs that are prescribed in the system does carry with it some risk of unnecessary increased costs, unnecessary increased delays. And if this formulary does do that, we think it's really important to identify that so that we can make sure to fix that if that is a problem that's created.

And we would just close with another comment about the education point that was raised by someone else. May or may not need to be in the actual regs themselves, but we do see a real problem out there in the system with people struggling to cite to the MTUS correctly enough to get treatment approved. And there are a variety of reasons for that, but with something like this, that we've got a system right now that a lot of people are struggling with and trying to figure out how to cite correctly to get a treatment approved, and we're now going to make it more complicated, and we're going to make it more restrictive. And that's concerning, but we do think a lot of

that concern could be addressed by just a massive education process.

And I know that there's a plan in place to do that, but we would just stress the importance of that and really putting some thought into making sure that we're going to physicians and getting to them ahead of time and giving them enough time to learn about all of this that is coming so that they're not just kind of caught flat-footed when all of a sudden things start getting denied, and they're not totally sure why.

And would just echo the comment that we certainly wouldn't object to a 6-month delay. We do think that the statutory language probably would allow that, and there are a lot of moving parts here and a lot of questions raised that an additional 6 months probably wouldn't really hurt, but it does carry the potential to really help injured workers.

So thank you.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you very much.

Surprisingly, I have reached the end of the list of everybody who wanted to testify. So at this point, I would like to invite anyone here who has some comments on the formulary, whether you're in the front row or sitting in the back row, to come up and offer some comments.

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DEVIN MOTLEY

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Good morning. My name's Devin Motley. I work for myMatrixx Workers' Compensation Pharmacy Benefits Manager, and just to echo everything everybody else has said, the work that's gone into it, you know, thank you all.

The one thing that I want to point out working for a Pharmacy Benefits Manager, I'm relatively new to both work comp and pharmacy benefits. And a unique perspective to it is that I see what the Division did with the regulation is they're trying to guide behavior of doctors, you know, by the MTUS whether it's compound, whether it's physician dispensing, whether it's brand, generic. You know, we're trying to promote best practices evidence-based medicine, and everything is addressing doctors, and the stick that the Division gave in the regs is retrospective review. That whenever a doctor doesn't do anything according to MTUS, they're not going to get paid. And that makes complete sense, and I agree with that.

The problem is is that the way we do business today, the way point-of-sale pharmacy, mail order, and that sort of thing works is these doctors have already been paid. That Pharmacy Benefits Management companies, we're stepping up, and we're paying these bills, you know, because we have to to pay them in accordance with, you know, time lines for whatever it might be.

So what happens is that Pharmacy Benefits Management companies get stuck holding the bag for these regs and, you know, it's not the way that the Department intended it to happen. It's just a fact of life of the way that business is done today.

So by giving that retrospective review hammer, you know, in the regs, it's going to really, really hurt PBMs. And with the way the fee schedule is already structured in California, you know, we could leave the system. And I'm not saying that me -- my company is going to, but, you know, it has to be, you know, PBMs provide a lot of really useful services to the system. We do clinical review, drug review, formulary, all sorts of useful things. We process things to the pharmacy, and I think the Division acknowledges having the regulations. And enforcement says that, you know, we can't put a more restrictive formulary on top of the MTUS formulary, and that's fine, but it's the retrospective review hammer. And I really don't think it's going to cut down on doctor behaviors the way the Division wants it to because these doctors are going to get paid anyways.

So thank you.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Would anyone else like to offer comments?

All right. Well, at this time, it's 10:50. I think what I'll do is take a 10-minute break, and if anyone else shows up

and would like to offer any type of comments, we'll take them at that time. So we'll be back in 10 minutes.

(Recess taken.)

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: We'll go back on the record, and at this time, again, I'd like to offer anyone the opportunity to offer comments -- oral comments on our formulary.

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MARY ELLEN SZABO

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Hi, my name is Mary Ellen Szabo, and I'm with Enstar Group, Paladin Managed Care, and I think our organization agrees with most of what everyone has indicated here about the time frame that is going to be needed to fully implement this and the education of providers, which I think is a huge gap in California.

Wondered if there might be some consideration for some kind of a trial or a follow-up date in which you can allow the organizations and the claims administrations to provide for you the gaps that are present in the system that you do implement, whether there's an increase of drugs on a level that they can't control, whether the injured workers are finding that there's additional delays, whether the information that comes between who's deciding whether it's adhering to the MTUS guidelines or not.

I see a little bit of a gap in there whereby the rule says that the preferred drugs still need to adhere to the MTUS guidelines, and I think there's going to be instances in which that might fall on a pharmacy. If you have a PBM involved, a PBM may be able to control that to some degree, but it might just fall into a lot of -- an increase of retrospective reviews because things are being dispensed that aren't part of the industrial injury.

So we would like some consideration if we can come back in a quarter or six months from the day we go live and see what some of the gaps are. Thank you.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Anyone else?

Very well. If no one else is going to testify, this hearing will be closed. The opportunity to file written comments will stay open until 5 o'clock this afternoon. Again, if you do have written comments, please be sure that they are received at the Division. We're on the 18th floor. You can send them to us by e-mail or hand-deliver them -- your preference. As I said, 18th floor.

So I'd like to thank you for your attendance and your input here today, and I'd especially like to thank our DWC staff for their work.

This hearing is now closed.

(The proceedings adjourned at 11:06 AM.)

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REPORTERS' CERTIFICATE

We, the undersigned Official Hearing Reporters for the State of California, Department of Industrial Relations, Division of Workers' Compensation, hereby certify that the foregoing matter is a full, true and correct transcript of the proceedings taken by us in shorthand, and with the aid of audio backup recording, on the date and in the matter described on the first page thereof.

Dated: May 8, 2017
Oakland, California

/s/ Rex Holt
Rex Holt
Official Hearing Reporter

Dated: May 8, 2017
San Francisco, California

/s/ Emily Hatton
Emily Hatton
Official Hearing Reporter