PDBM Chapter 6, The Part D Formularies Awaken

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Stacey Plizga: Our next speaker will start us off this afternoon by providing us with an understanding of the revisions made in Chapter Six of the Medicare Prescription Drug Benefit Manual as well as respond to questions received about the update. It is my pleasure to introduce to you Lieutenant Commander Marie Manteuffel and Robert Dombrowski.

LCDR Marie Manteuffel: Good afternoon. I am Lieutenant Commander Marie Manteuffel. I am an officer in the U.S. Public Health Service Commissioned Corps and serve at CMS in the Division of Part D Policy. As you just heard, I'll be presenting this afternoon on the recently revised Chapter Six. And about halfway through this session I'll be joined by my colleague, Bob Dombrowski, who will speak more to the formulary updates, formulary reference file, and utilization management. Our agenda for this session is noted here. And it was suggested we needed a catchy title, especially being right after the lunch session, so, without further delay, "Chapter 6: The Part D Formularies Awaken."

Okay. Chapter Six is a key reference for Part D sponsors on the administration of the Part D program. The first Chapter Six came out for comment in 2006, the first year of the Part D program. And it has grown and been revised over the last ten years. The chapters are available

online through the Online Manual System. And here is a screenshot of the cms.gov page on manuals. From here, you can see where the red arrow is pointing, you would click on "Internet Only Manuals" along the left-hand side of the screen. When you do that, it will take you to the different listing of the publications available. And under "Publication 100-18" is where you'll find those specific to the Part D program. So, when you click on "100-18" you see the table of contents for the various chapters available.

So, here in front of you, this is the 2016 version. You should see, when you're pulling this up, the red date underneath should say 2016. That's our most recent version. And consistent with past revisions, this revision covers three main areas, definition of a Part D drug, Part D exclusions, and formulary requirements. There are also four appendices, which include a Part D drug summary table, a discussion of B versus D coverage issues, a list of the most commonly prescribed drug classes for the Medicare population, and, new in this version specifically, a listing of various scenarios when transition supplies may or may not be warranted.

So, to start the revision process, we did some redlining. And looking back over the last few years, we wanted to see what policies have changed, what memos have been issues, what call letter policies have been announced, and what regulations have been finalized, and, with that, what needed to change and be updated in the Chapter Six to make it current with current policies. I would like to stop here and truly thank everyone who reviewed and provided suggestions during this process. Feedback was extremely helpful, and comments were carefully considered before finalizing this version.

Since this was such a comprehensive revision, we also took the time to clean up some formatting and grammatical issues. So when you open the chapter and you see some different language in red that appears new, it

might be less about a new policy or a revision. It might just be grammatical or verb tense or list formatting issues as well.

Okay, so starting here in the following slides, we'll walk through some but not all of the sections with revisions in this 2016 update. When you access the chapter online or download it, you'll see any of the new language in red text. So we'll start with section 10.3, Commercially Available Combination Products. This section was updated in line with changes made in the final Part C and D rule in 2014. Notably, we wanted to clarify, this section applies to commercially available combination products meant for broad distribution. It does not apply to extemporaneous compounds. This section is more talking about kits or bundles where multiple units or items are packaged together and intended to be dispensed as a single unit.

Okay, so if you can get your voting device ready, we have our first question for the audience. So, consider this scenario: a new hypothetical drug, Super Strong Bones plus B, was just approved and hit the market last month. Mrs. Jones arrives at the pharmacy with a prescription for Super Strong Bones plus B. Is this a Part D eligible drug? And I will hold here for a minute while you log your votes.

We see B growing. C. Okay, so we're seeing a lot of variety in the answers, which is great. We kind of made this one a little tricky on purpose. So, to think it through, if the FDA approved Super Strong Bones plus B in this combined form, whether both ingredients are in one tablet or whether they're separate in separate bottles but being dispensed together as a kit, if it was approved in that form and it is approved for Mrs. Jones' condition, then yes, a Part D plan could cover this drug. So the correct answer, there's some truth in A, some truth in B, but really, for this section, what we're looking at is that Part C part. It really depends on how the kit or the package was approved by the FDA. So thank you, everyone, for voting.

Moving on to section 10.4, this is the section specific to extemporaneous compounds. Some of the updated Chapter Six language is included here on the slide in front of you. And to give one example, looking at the second bullet, for a Part D compound to be considered on formulary, all ingredients that independently meet the definition of a Part D drug must be considered on formulary. Said another way, a claim for a compounded drug needs to be treated as one claim. It's either all on formulary or not. Even when the sole Part D ingredient is on formulary, a sponsor does not have to automatically list any compounds with that ingredient as on formulary. Sponsors can choose to only cover compounded medications by exception.

So if you want to get your voting devices ready again, we have a true/false question. True or false, Part D sponsors must consider extemporaneous compounds, including at least one Part D eligible ingredient as on formulary. And we'll hold here for a minute.

So it looks like a pretty even split so far between the people responding. The answer for this one is false. Sponsors technically do not need to consider any extemporaneous compounds as on formulary, and instead may choose to review individual ingredients and medically appropriate indications on a case-by-case basis. Section 10.4 in the chapter does go on to offer sponsors guidance on how to handle both formulary and non-formulary extemporaneous compounds.

So, moving on to section 10.6, Medically Accepted Indications. Part D sponsors must reference all CMS-recognized compendia to determine whether there are any supportive citations prior to determining that a drug is not being used for a medically-accepted indication. And bullet number two, all Part D sponsors should consistently utilize prior authorization for those drugs with the highest likelihood of non-Part D covered uses, as detailed in section 30.2.2.3, unless plans are able to reliably use tools other than PA to determine appropriate coverage for the drug.

In section 10.6, we talk about Part D sponsors' responsibility to determine whether a drug is being dispensed for a medically-accepted indication. CMS is not at the point of requiring PA on all drugs to confirm diagnosis. Consistent with documents CMS has issued previously, we do ask sponsors to consider their experience with determining MAI, and to utilize PA for other reliable tools or available documentation to make determinations about those drugs with the highest likelihood of non-Part D covered uses. There is not one be-all, end-all list of drugs, rather we look to sponsors and their P&T committees to thoughtfully consider their experience with the program and to balance an appropriate use of PA and other tools. And, as noted here and in the chapter, there's more detail in section 30.2.2.3, which we'll touch on in a few slides.

So, another voting question. In this scenario, would this drug be for a medically-approved indication? So this is a little confusing. I'm not sure if it's back on the other slide. Okay, so I will read the scenario. It didn't appear here. So, in the case of a drug where the indication is not on label, the indication is supported in AHFS DI but is not supported DrugDex, would its use be considered medically accepted? So I'll say that one more time since it's not on the screen. The indication is not on label, the indication is supported in the American Hospital Formulary Service Drug Information compendia, but is not supported in DrugDex; would that use be considered MAI? And it looks like a majority of the people responding did get that correct. Yes, if there is support in one of the recognized compendia, this would be considered MAI.

Moving on to section 10.6.1, Retrospective Determination of a Medically Accepted Indication. One retrospective review of point-of-sale claims adjudication determines that a drug was dispensed for a non-medically-accepted indication, the PDE should be deleted and accumulators adjusted. As stated here on the slide, we highly encourage everyone to review also chapter 18 on this topic. And there were also some guidance documents from 2013 related to this from the Medicare Plan Payment

Group, for more information. And so, again, just multiple publications, multiple online resources to be considered.

So, sticking with this same section, just for another minute, what's on the screen in front of you is an example taken straight from the chapter, so just to kind of walk through what this looks like. When it's not reasonable to expect a Part D sponsor to require PA to ensure that a drug is being used for an accepted medical indication, CMS would not expect the sponsor to recover payments made to pharmacies or attempt to obtain reimbursement from enrollees. However, when retrospective review of POS claims adjudication determines that a drug was dispensed for a non-MAI, the PDE should be deleted and accumulators adjusted. And, again, I'll point you to chapter 18 and 2013 guidance previously released on these topics.

So, moving into the next section, section 20 of the chapter, we'll begin with section 20.1 Excluded Categories. There weren't a lot of changes to this section generally, but I'll draw your attention to the second bullet on the screen, which is some revised language that was used to clarify coverage around cough and cold medications given the number of questions we receive on this area specifically. To restate some previous guidance on this issue, any prescription medications containing a cough suppressant are not eligible under basic coverage. For prescription medications containing an antihistamine, with or without a decongestant but not including a cough suppressant, these could potentially be covered if being used for allergies and not being used for cold symptoms. It is up to the plan sponsor to use the tools at their disposal to confirm a medically appropriate indication.

So we have another voting question at this point, another true or false. A standard Part D plan cover a nasal decongestant for a member with a history of diabetes, high blood pressure, and gout, whose breathing is labored due to lasting congestion from a head cold lasting two weeks. So

I'll hold here while you vote. And it looks like a majority of people are getting this right as well. The answer is false. In this scenario, the decongestant is being used to treat cold symptoms, which is an excluded category.

Moving on to the next section, 20.2, this is pertaining to drugs covered under Medicare Part A or Part B, notably hospice or end-stage renal disease. These two topics have been presented on in previous conferences and we would point you to the exact language in the chapter here. It was revised largely in line with guidance released in 2014.

Moving on to section 30.2.2 Formulary Benefit Management Tools. In a few more minutes, my colleague Bob Dombrowski will be speaking in much more detail about formulary and formulary policies. But I did want to briefly note some changes made in section 30 of Chapter Six. Of note, the language in front of you, while this is not a change in policy, we clarified that when an issue related to a POS edit is resolved at the point of sale allowing the claim to adjudicate under Part D, the claim transaction does not constitute a coverage determination. Conversely, in situations where the patient or prescriber makes a verbal or written request for coverage of a drug subject to prior authorization or other UM restrictions to the plan sponsor, that is a coverage determination and the plan must process it accordingly. And, again, I'll point you to chapter 18 for additional details.

Also in section 30 of the chapter, in an attempt to make clearer what types of edits do and do not need to be submitted to CMS for approval, we broke this down into a few additional subdivisions. So, in section 30.2.2.1, we more clearly identified the three types of POS edits, hard, soft, or message only. We added additional language to detail for sponsors the differences between PA, step therapy, and quantity limits. And there's also new language about opioid-specific safety edits. In section 30.2.2.2, we talk about edits not requiring CMS submission and

approval. This includes information on some safety edits as well as cumulative acetaminophen or APAP edits.

And the next section 30.2.2.3 is talking specifically about application of prior authorization. And back on slide 16 is when we promised more information on what was meant by highest likelihood of non-Part D covered uses. The bullets here on this slide list three areas of note, high likelihood that coverage is available under Part A or Part B, high likelihood that the drug is excluded from Part D coverage, high likelihood of use for non-medically-accepted indication. We've discussed each of these already. Also, this section of the chapter goes on to list non-allowable practices, specifically things that cannot be included, practices that cannot be done related to prior authorization forms.

Moving on to section 30.3.3.1, we wanted to note section 30.3.3 pertains to midyear formulary changes. We've received a number of questions confusing midyear with year-to-year changes. Again, I won't get into too much detail before Bob on formulary changes, but I will just note that in this section, specifically 30.3.3.1, we provide additional detail on what constitutes the negative formulary change, which you can see defined here on the slide. Unlike positive formulary changes, which we note can be implemented immediately, such as when a new drug hits the market, negative formulary changes after the start of the contract year are more concerning, so we have additional details here. For example, in the definition above you'll see that we would consider a drug going from tier two to tier four during the course of the year a negative formulary change. Similarly, we would consider a midyear plan change from a 60-pills-per-30-day quantity limit to a 30-pills-per-30-day quantity limit as a negative formulary change. Both would be subject to all formulary change notice requirements.

So, sticking with this section just a bit longer, we'd like to clarify additionally based on some questions we received after the publication.

This passage specifically -- and I can give you a moment here to read it -- this passage refers only to approved exceptions, not prior authorization. I will say that again. This section refers only to approved exceptions. If the duration of the plan granted exception is included in the original exception approval letter to the member, the plan does not have to notify the beneficiary again 60 days in advance of its expiration.

So, for example, if the plan sent a letter stating, "Mrs. Jones, your prescription for two tabs daily of the ten milligram-strength has been granted an exception and will be covered through the end of this year." That plan does not need to send a second letter on October 31st reminding Mrs. Jones that that expiration is expiring. However, if the plan sent a letter only stating that the prescription for two tabs daily has been granted an exception, that plan should send a second letter reminding the beneficiary when the exception expires 60 days in advance. Lastly, we wanted to remind plans that, at this time, mailed hard copy letters sent via first class mail are the only way to satisfy this notification requirement.

From here, we'll move on to section 30.4 Transition. The bottom line with this, the purpose of the transition policy, is to address situations when an enrollee's ongoing drug therapy could be potentially interrupted by a drug being non-formulary. However, just because a member's drug therapy could potentially be interrupted does not mean that the member will necessarily receive a transition fill. I would also like to clarify the above text based on questions we received after publication. Whenever the -- this passage above, notably number two, refers, again, only to approved exceptions, not prior authorizations. Whenever the exception expires, a member would be eligible for a transition fill, whether the member was informed of the exception in an initial determination letter or if they were notified when the plan sent a second notice 60 days prior to the exception's expiration date. Of note, this does apply to exceptions expiring midyear.

To give another example, if Mr. Smith was authorized a six-month exception to cover drug X, if Mr. Smith goes to fill another supply of drug X seven months into the plan year, assuming that exception started on the first of the year, Mr. Smith would be authorized to receive a one-time transition fill of at least a 30-day supply, and the plan should then follow up with a transition letter. Lastly, we would like to say that while Chapter Six doesn't explicitly address the transition fill for expiring prior authorizations, we note that it may be a best practice for sponsors to provide a transition fill for at least certain PAs that are expiring in order to avoid interruptions in therapy.

So, moving on towards the end, section 30.4.10.1 is new in this version. This is new language for 2016, Prescriber Notification of Transition Fills. This was added because, as you can see in the new language in front of you, we feel the prescriber is in the best position to advise the beneficiary of the benefits or risks of switching to a different medication. The chapter ends with the appendices. As you see, appendix A has been removed in this version. Appendix A was Common Acute Care Home Infusion Drugs. CMS is no longer maintaining this tool, and we have chosen to remove it in this version. However, new in 2016 is appendix E, Sample Transition Supply Scenarios and Eligibility. And we will walk through an example from this chart.

So, as an example, we cut a few rows -- I believe the top two rows -- from the appendix above, and will walk through, from left to right, the top scenario and the bottom scenario. So, starting on the top row, it is coverage year one and the beneficiary is with sponsor A, plan ABC, and their drug is on formulary. In coverage year two, on the top row again, they stay with sponsor A, plan ABC, and their drug is still on formulary. Moving to the third column, the result, no, this beneficiary is not eligible for a transition supply. There was no change in formulary. Next we'll do the bottom row.

So, again, it is coverage year one, the beneficiary is with sponsor A, plan ABC, and their drug is on formulary. Middle column, coverage year two, they stay with sponsor A, plan ABC, but now that drug is non-formulary. Moving to the third column, the result, yes, that beneficiary would be eligible for a transition supply. I will conclude my remarks here and turn it over to Bob Dombrowski for more information on formulary and utilization management. Thank you.

Robert Dombrowski: Thank you, Marie. And good afternoon. My name is Bob Dombrowski and I work in the Division of Formulary Benefits Operations here at CMS. Before I'd like to begin, I would like to let you know that I'm using some Star Wars references as well in my talk. I've included quotes from Yoda, because I thought he was pretty inspirational and had a nice positive vibe going. Always, you know, you learn a lot from Yoda quotes. I do want you to know that someone suggested that I use some Darth Vader quotes. And while at times I think his quotes are really humorous given the context of the situation that Darth Vader is in, I'll try to keep away from the dark side.

So I certainly hope my talk keeps away from the dry side of things for you. I hope that this is a very informative talk for you. In the last week, we published a memo on frequently asked questions for Part D formularies, and hopefully you had a chance to look at it; and if you hadn't, that'd be a very good reference for you. Part of my talk today, two -- we'll talk about the formulary reference file -- two years ago, we published a very good reference for you, I think it was on April 8th, on frequently asked questions regarding the reference file. So you have two good publications that a lot of this talk will be based on.

The general topics that I'll be talking about today will be obviously providing some guidance on quantity limits. There have been changes over the past few years, so hopefully we can provide some clarification for you there. Also, some questions that have surrounded formulary updates

and how formularies can be updated. Reference file, there have been a number of questions on the reference file, and, again, that reference from a couple years ago would be very beneficial for you. And the last thing is some points and pointers on utilization management criteria updates.

It would have been nice if I had that slide up first, but. So these are the four topics I'm going to be talking about today, quantity limits, formulary updates, reference file, and utilization management. So a general question, how the submission and review of quantity limits has changed. Two years ago -- I guess it was actually about -- actually new for 2016, it seems two years ago, but it was 2016 -- we introduced the concept of a type two QL, quantity over time. So that was kind of brought about through industry having some questions with adjudication issues, particularly for drugs that were provided in timeframes that may be less than a 30-day supply or greater than a 30-day supply, something that didn't quite fit. So we introduced the type two QL. New for 2017, we've introduced this unit on a reference file, a quantity limit unit, that we urge everyone to use when they're going over and establishing their quantity limits.

So, while I'm talking about some things that changed, some things haven't changed. QLs -- this has always been the case -- for QLs that allow the dispensing of a given drug up to the FDA-approved maximum daily dose, they're not required to be submitted to CMS. So if a maximal dose of a drug is 80 milligrams and you have 80 milligrams, you can always apply safety edits for those doses exceeding 80 milligrams; you don't need to apply quantity limits. If you needed to apply quantity limits for dose optimization, that would be an area where you could apply quantity limits.

Sponsors should submit quantity limits based on the daily dose over a one-month period for nearly all drugs that are subject to a QL edit. This would be predominantly type one or daily dose quantity limits. So, in

reference to daily dose quantity limits, you would want to -- you could submit it one of two ways. One could be on a daily basis.Let's say there's four tablets per day. You could submit four tablets for one day, or you could submit 120 tablets for 30 days. Either way you submit that QL, we interpret it as being a month supply of medication. So it's important to know, though, if you submit it as four tablets per one day, that's what's going to be showing in Plan Finder, and it will show on your marketing materials as well. And if the benefit for a drug is supposed to be a monthly dose of medication, we don't allow plans to restrict it to less than that for a specific or unique drug, if the drug is really intended to be given on a daily basis.

"Always two there are; no more, no less." That's a quote from Yoda. Somebody wanted me to impersonate Yoda, but I felt a little uncomfortable. I don't know how good it would have gone over, so. Again, type one QLs are based on daily dose. And the majority of QLs are submitted as type one. And actually, the introduction of type two, again, has been for sponsors who've had issues with doses or quantities that are other than a daily dose. And some of these have been migraine medicines that aren't given on a daily basis. Type two QLs should rarely be used. If you've not had any problems adjudicating as a type one QL, you can continue to adjudicate your QLs and submit your QLs as a type one QL. The use of type two QLs will be subject to review and approval because some drugs are given on a daily basis, and a type two QL would not really be reflective of something that's given on a daily basis.

So, new for 2017, sponsors should use this QL unit as a basis to submit their QLs, and it's on the reference file. The reason why we did this is because there was some confusion for sponsors, particularly with unique dosage forms, like reconstituted vials and certain inhalers that weren't fitting the submission type that we had on our reference file for grams and MLs and certain syringes. So this is kind of a nice way that we can both communicate in the same way. And the designations that we're using are

based on the NCPDP billing unit standard logic, and sometimes that can be kind of confusing in the sense that something could go either as an ML, some category of each could be an ML or it could be each, and you'd have to look at the NCPDP billing unit standard for the definition to see what that unique quantity or drug -- how that should be submitted.

Okay, this is a first question. Are Part D sponsors prohibited from making changes to their formularies between the summer update window and the beginning of the plan year? I'm liking what I'm seeing here. You know, at first, there was 150%, but. Okay. Well, I think we have that. We got that. This is something you're not prohibited from making changes to. Your formulary between summer update window and the beginning of the plan year.

So here are some good Yoda quotes that I think are kind of relevant to formulary updates. "Difficult to see. Always in motion is the future." And, obviously, this plays out with all the different new drugs and things that are always coming, and actually policies and things that are always changing. "Always pass on what you have learned." We understand that there are lots of new people who come on to organizations and within CMS, and we share our expertise and knowledge and we pass on what we know. And "Many truths that we cling to depend on our point of view." And, as a result, we tried to publish some frequently asked questions that you asked, to clarify some of these, so that there's more open communicative process, so that you can see where we're coming from as well.

So the formulary updates prior to the start of the plan year, the summer limited update window is the final opportunity to submit negative formulary changes prior to the start of the plan year. And these would be maintenance changes, when new generics are added to the FRF. So this would happen usually at the end of July, beginning of August. Right now, we have it pretty much set for the end of July. So these are opportunities

for you to take a branded product off the formulary and put in place a generic on formulary. So this is specifically talking about negative changes.

Formulary updates prior to start of the year for enhancements, these can be like adding newly approved drugs. These can be added in any time, including before the start of the plan year. Marketing materials must be updated. So let your -- let the public know that these are drugs that you're marketing and that you have on your formulary, even though it wasn't what you initially had submitted to us in July. Changes must be reflected in the first available HPMS submission, and changes will not be reflected in Medicare Plan Finder until the change is made in HPMS. So, until we see it, it's not going to be reflected in Plan Finder.

So, a couple of questions. When can plans submit negative formulary change requests and how long does it take to approve an NCR? Plans can submit NCRs basically from January through July. They may opt to notify affected enrollees and other required parties that they -- at the same time they notify CMS. So you can submit this change and, at the same time, notify beneficiaries, but, just as a caution, just make sure that the change is consistent with CMS requirements in order to avoid resending or sending change notices.

Brand changes may be requested before a newly approved generic is added to the FRF. So if you know of a generic that has come out, you can actually submit this change. However -- and it doesn't have to be on the FRF yet. However, that change cannot be implemented until the offsetting generic is added to the formulary. For 2016, CMS currently approves maintenance changes. Actually, it's around maybe a little over 12 days right now. And, for 2015, we put out, you know, our frequently asked questions. It's about 15 days for maintenance and a little over a month, about 37 days for non-maintenance requests.

How long does it take for a drug to be added to the FRF? This is kind of complicated, not a direct answer I can provide to you for this. One of the most common questions we receive, both from plans and advocates, and even colleagues, is when will this drug appear on the reference file? Unfortunately, we can't provide the exact date because this time varies and is usually not within our control. Our colleagues at FDA approve the drug, and there's typically some lag time between approval and the launch date. To create the FRF each month, we use a number of data sets, including the FDA's NSDE file, RxNorm downloads, and NDC databases.

Once the drug is available in these data sets and is on the market, we evaluate it for the FRF. If we determine that it could meet the definition of a Part D drug, it will be added to the FRF, depending on when the drug appeared in the data set and when it's added. On the left side of the diagram, as you see, while we're going through these iterations and decisions, sponsors are doing the same. So the P&T Committee can review at any time, even earlier than the market launch date, once they know something's available. But the review should be done within 90 days of market availability, and a decision made within 180 days for non-protected class drugs and 90 days for protected class drugs.

Okay. Can plans cover drugs that are not on the FRF? You know, and these are yes or no questions, and you've seen the 50%. Okay. Okay. All right. Well, I think the majority of you have gotten that. Yes, you can cover drugs that are not on the formulary reference file.

Can utilization management be applied to drugs that are on a plan's formulary but not on the FRF? Okay. All right. Again, I think everybody gets that pretty much. You can have utilization management on a plan's formulary. So plans can add drugs to their formulary that are not on the FRF, such as drugs that are new to market. UM may be applied to these drugs. Additions can adjudicate at the point of sale immediately, and must

be reflected in updates to marketing materials. Formulary additions should be submitted via HPMS as soon as they appear on the FRF. An FRF ad request must be submitted to CMS for covered drugs that are not yet on the reference file. So, once you've added a drug that you know is not on the reference file, it's nice to let us know, "Hey, we're covering this, or should we consider it to be on the reference file?" If UM is requiring the edits and criteria be reviewed upon HPMS submission, then that may require modification by the CMS approval.

Okay. Can UM or safety edits be applied to drugs that are non-formulary? PA, step, or QLs within the FDA-labeled dosing guidelines must not be applied to drugs not on the formulary. Non-formulary drugs are subject to general formulary exception requirements. However, safety edits, such as maximum dose limitations, cumulative MED, may be applied to non-formulary drugs. So, some of the safety edits that we talked about before certainly can be applied.

Is a beneficiary who receives a transition fill of a protected class drug that has a PA or step requirement exempt from those requirements for subsequent fills? Okay. Well, this would be a question that I think we need maybe a little clarification. If a sponsor allows an initial fill of a protected class drug and it cannot determine at the point of sale that an enrollee is not currently taking the drug during transition, the sponsor shall treat such enrollees as currently taking the drug. Therefore, any protected class PA or step requirements for new starts are no longer applicable after the first fill has been provided.

Can plans routinely update UM criteria? And do UM criteria updates require CMS approval? Existing PA of step criteria should only require updates in rare and extraordinary circumstances. Sponsors should perform necessary QA checks in advance of HPMS submission in order to avoid having to update during the plan year. Criteria may be updated in

a manner to allow the inclusion of additional drugs without the need for subsequent criteria updates.

We put out, in January, a memo for utilization management updates, obviously a removal of a restriction or addition of drugs to existing criteria, kind of enhancements. We were having issues with altered templates and folks just submitting changes for grammatical errors, which we really don't want to have to review.

One of the things for hepatitis C, the guidelines have come out in the last two years have increased from about 48 pages to 227 pages. And I think that, in the market, there's been a lot of new products that have been entering the market and things are in a constant flux. Often, the guidelines have been updated at least a couple times per year. And we're all in a catch-up period of trying to have our criteria in sync. So we suggest that for hepatitis C criteria, maybe use a default criteria that will be applied consistent with current ASLD guidance rather than restating the information that's already contained within the guideline. It's hard, there are a lot of mistakes that are made and things keep changing with that guidance. So, with that, I would like say, "May the force be with you." And a friend wanted me to share this with you.

"Remember, the force will be with you."

So, for questions and resources, you can contact regarding Chapter Six, the Part D policy, at PartDpolicy@cms.hhs.gov. And for the Part D formularies, it's PartDformularies@cms.hhs.gov. And I don't think we have much time for questions. Okay. All right. Thank you.

Stacey Plizga: Okay, we do not have time for questions right now; however, we will have time at the end of the day to address questions to both Marie and Bob. So thank you very much. We are going to evaluate the session, so go ahead and go to your phones or your tablets, computers, and enter "A" and

follow the instructions. Did you have questions for them? Please go ahead and send them in to the SurveyMonkey link, and we will address those later.