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TRANSCRIPT

Vanessa Duran

**Director, Division of Policy, Analysis, and Planning, Medicare Drug and Health Plan Contract Administration Group
CMS**

Good morning. It's so great to be with you all this morning. I'm so early in the agenda, not right after lunch, while you're all still inspired by the key-note address and highly caffeinated, bright eyed and bushy tailed.

The purpose of my presentation this morning is to provide a very high-level overview of the recent contractor 2012 Part C and D final rule that we issued. My goal today is to be brief, to leave plenty of time for Q&A at the end of the presentation. This effort to put out this final rule was a nearly year-long effort, highly collaborative across the C&D folks, managers, and a number of analysts throughout the center, and because it is so broad in scope, I strong-armed folks sitting up here with me to answer Q&A at the end of the session. So again, my goal is to run through these fairly briefly to leave you plenty of time for Q&A.

You will receive additional information about how some of these provisions are being operationalized in the presentations that will follow me today, specifically in the presentations on quality measurement and plan ratings, also Part C and D bid review, as well as the out-of-pocket cost tool.

The final rule displayed at the office of the Federal Register a week ago, April 5th, we expected to publish in the Federal Register later this week, and the rule is effective on June 6th, which should be a date that rings some bells for you all. Most of the provisions in this rule are effective -- or rather, applicable to the contractor 2012. There are a few exceptions.

As you're aware, the rule was released right around the same time as the final payment notice and the final call letter. This is similar to the approach that we took last year, and this is our second year of what we expect to be an annual rule-making cycle that will conclude right around the same time every year to make sure that you all have plenty of time to consider all policy payment-related changes, you know, and any additional operational information you need to adequately prepare your bids and prepare for bid submission the first Monday in June.

The scope of this rule, as I said, is fairly broad. It not only implements a number of changes affecting the Part C and D programs coming out of the Affordable Care Act, but it also implements a number of other changes using the existing statutory authority that we had.

The final rule is organized schematically rather than by applicability. They're the Part C, Part D, or Cost Plan Programs, and that's how I have organized this presentation. I have 45 minutes and we had over 50 provisions. As you can imagine, we're just going to pick a few highlights and focus on these specifically.

As I think I've mentioned, a number of the provisions in this rule were related to implementation of the Affordable Care Act. Nearly half of them in this rule were. But the rule also operationalizes other programmatic changes that help us oversee and manage our programs better and, we hope, also to help to improve the beneficiary experience under the Part C, Part D, and Cost Plan Programs.

So let's dive right into implementing provisions of the ACA, and specifically, to start let's focus on the MA cost-sharing related changes. This rule codifies the ACA provisions related to cost sharing under MA plans, such that cost sharing does not exceed cost sharing under the original Medicare program.

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The Affordable Care Act spoke to three specific provisions, and the way that we've codified that in the rule is applicability to first chemotherapy administration services, which we've defined to include chemotherapy drugs, radiation therapy services, and other related chemotherapeutic agents.

The second category is renal dialysis services, and the third is skilled nursing care, which we've defined as skilled nursing care facility services, specifically during any period in which original Medicare cost sharing applies. So that is specific to SNP care provided after the first 20 days. We also use this rule as an opportunity to extend those provisions to 1876 cost plans.

This rule also extends to MA plans, as well as to Section 1876 cost plans; the ACA requirement under which certain Medicare preventive services must be offered at zero cost-sharing to fee-for-service enrollees. So beginning for contractor 2012, MA enrollees must have access to the same preventative services in that work as fee-for-service enrollees currently have at zero cost sharing. The rule also clarifies and codifies our new authority not to accept any and all bids we receive, as well as to deny bids that demonstrate significant increases in cost sharing or decreases in benefits.

Now the regulatory language tracks the statute pretty closely, but as we finalized these provisions we heard your message loud and clear that plans should be aware, as early as possible, prior to bidding how we intend to operationalize these requirements. So how are we looking at plans to make sure that they're meaningfully different from one another, and how are we making sure that year-to-year your plans are not demonstrating significant increases in cost sharing?

The session on Part C and D bid review, after lunch this afternoon, is going to provide you with additional detail regarding our use of the out-of-pocket cost methodology, as well as the total beneficiary cost methodology for 2012. Most of this information was articulated in the final call letter and will be spelled out in further detail by my colleagues.

Jumping ahead to enrollment, the final rule codifies the ACA's changes to simplify beneficiary election periods. The first of these is the change to the annual election period, which, effective for contract year 2012, will shift from an October 15th to December 7th window. In addition, the ACA eliminated, effective this year, 2011, the old open election period that was available during the first three months of the year. Instead, there is now a new Medicare annual disenrollment period, the MA-DP, which occurs annually in the January 1st, to February 14th window. It has a much more limited scope. Under the MA-DP, MA enrollees may disenroll to original Medicare for their medical coverage only, and during that period, may also elect to enroll in a PDP.

Next, I want to focus on some Part D provisions. This rule codifies statutory provisions that allow PDPs and MAPD plans to waive a *de minimis* monthly beneficiary premium for LIS-eligible enrollees. The rule also prohibits us from reassigning LIS individual who is are enrolled in a plan that has a premium greater than the benchmark as long as that premium, that amount of excess premium, is *de minimis* and that plan has voluntarily chosen to waive the *de minimis* amount. This statutory provision was effective beginning plan year 2011.

The final rule also establishes rules for an income-related monthly adjustment factor known as the Part D IRMA that is added to the monthly Part D premium for individuals above certain income levels. The Part D IRMA provisions were also effective January 1st of this year. The rule also codifies changes to revise the Part D benefit structure to close the coverage gap over time, and it codifies the elimination of the Part D cost sharing for individuals receiving home and community-based services under home- and community-based waiver under Medicaid. What this means is that individuals receiving services under home- and community-based waivers will be on a level playing field with institutionalized individuals who currently have zero cost sharing for their Part D drugs.

The rule implements a number of payment-related changes that are specified in a great deal of detail in the final payment notice for 2012. So I'd like to focus in particular on the fact that the rule makes changes to the calculation of benchmarks and to rebate amounts, and specifically to the application to quality bonus payments. These are the rules that will apply after the qualify bonus payment demonstration concludes. As you're aware, that demonstration is in effect from 2012 to the end of plan year 2014.

The rule also discusses the methodology for using the current five-star plan rating system to determine QBPs, and it defines what it means to be a low-enrollment contract, as well as a new MA plan. It also discusses, in the preamble, our strategy for transforming the rating system in future years in order to advance what we believe will be a more ambitious and comprehensive quality improvement agenda, and again, you will hear a great deal more about this in the presentation following the break, so I'll leave it at that, other than to say that the rule also codifies an administrative review process for QBP payment and rebate retention appeals.

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Another provision in this final rule that generated a great deal of comment from a number of different parties was the provision that codifies statutory requirements intended to reduce wasteful dispensing of Part D drugs in long-term care facilities. We finalized that requirement, you know, after considering the significant number of comments that we received on that proposal as a requirement to dispense in 14-day-or-less increments. It was 7 day or less in the proposed rule. The requirement is also limited to brand-name drugs, and the final rule delays implementation of that provision until 2013.

This rule also codifies requirements for Part D sponsors to have a single uniform exceptions and appeals processes for the determination of prescription drug coverage. Plans are going to be required to provide instant access to these processes through a toll free telephone number, as well as electronically, including through their websites.

Part D sponsors will also be required to notify pharmacies about the need to generate a printed notice with information about how to contact plans to request a coverage determination, including a formulary exception when a prescription that cannot be filled at the point of sale is written.

I'm going to conclude this section on implementing provisions of the ACA by focusing on the special needs plans provisions for a moment. As you are aware, the ACA extended the authority to operate SNPs; that is, to limit enrollment to special needs individuals through the 2013 plan year. The rule also codifies the requirement that all dual-eligible SNPs, whether they're new, existing, or expanding, begin to operate with the state contracts by the end of 2012 for the 2013 plan year.

The rule also codifies the application of a frailty payment under case payment rules for certain individuals enrolled in fully integrated dual eligible SNPs or FIDA SNPs. It also codifies the definition of what a FIDA SNP is. And finally, the rule codifies a new requirement that all SNPs, whether they're new, existing, or expanding their service area, be approved by the National Committee for Quality Assurance beginning for contract year 2012, based on standards developed by the secretary. This final rule stipulates that evaluation of the SNP model of care specifically is to be the basis of that evaluation and approval.

And those of you who are operating or wish to operate new or expand your existing SNPs are aware that we just wrapped up the first cure process of the application cycle and are working very hard with your organizations to provide technical assistance to make sure that by the end of the second cure and by the wrap up of the application process your plans will be in good shape to have that approval.

So moving on, this rule contains about eight provisions that clarify existing regulations or implement new requirements that are consistent with existing policy guidance and help us to ensure that plans are attaining program goals. I'm going to focus on just a few of these for you today. The first of these is a prohibition, Part C and D program participation by organizations whose owners, directors, or management employees served in a similar capacity with another organization that terminated its Medicare contract within the previous two years.

We also clarify, consistent with sub-regulatory guidance in the non-contractor provider payment guide, that a request for payment from an MA organization by a non-contracted provider who is paid under a prospective payment system methodology under original Medicare is deemed to be a request to be paid at the original Medicare payment unless the provider has notified the MA organization in writing specifically that it wishes to bill less than the original Medicare payment amount.

This rule also contains a provision that requires the timely transfer of data and files in situations where CMS terminates a contract with a Part D sponsor. This is just a provision to extend current regulatory provisions for contracts that are terminated by mutual consent or by cause by -- for cause by the plan. Specific time frames for the transfer will be provided in guidance because, of course, every situation is very specific.

Although our regulations previously required physician review of adverse organization determinations or coverage determinations that involved medical necessity, they didn't really specify who had to conduct that initial determination involving medical necessity. So to that end, we modified our current regulations to require plans to use physicians or other appropriate health-care providers with sufficient medical expertise and knowledge of Medicare coverage rules for this specific purpose.

We also finalized a requirement to further enhance plans' clinical decision-making processing and quality assurance activities, and that is specifically for all organizations and sponsors to employ a medical director who is responsible for ensuring the clinical accuracy of all decisions involving medical necessity. That medical director will need to be a physician with a current and unrestricted license who practices medicine in any one of the 50 states, territories, or commonwealth, or the District of Columbia.

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Another important focus of this rule was to strengthen beneficiary protections and the beneficiary experience under our program. We had about ten provisions in the rule with this purpose, and I'm going to discuss most of them with you today.

The first provision I'd like to focus on is the codification of an existing sub-regulatory guidance requirement from the Medicare marketing guidelines that MAOs and Part D sponsors provide interpreters for all non-English and LEP, limited English proficiency callers. We also implemented new authority to require MA organizations to periodically provide to their enrollees a Part C explanation of benefits. This is already a requirement under Part D, and it's a modification of the proposal that we originally had in the proposed rule with respect to providing customized enrollee data to enhance beneficiary decision-making processes.

We intend to delay full implementation of this requirement until after we conclude a pilot program with a handful of organizations and use those experiences to inform the requirements for all MA organizations and future plan years.

You may recall that in our 2011 regulation we established for the first time in regulation a maximum out-of-pocket cost limit requirement for all plans, as well as a catastrophic limit requirement for PPOs, local PPOs in particular. Those requirements were, of course, stipulated in such a way that CMS annually makes determinations about what the maximum out-of-pocket cost limits are, as well as the catastrophic limits.

This final rule simply extends those requirements to regional PPOs, and our PPOs will be, as with all plans, subject to the requirements that CMS annually provides in the final call letter and which will be discussed with you in further detail in the presentation after lunch. This rule also requires and finalizes a proposal to ensure that Part D sponsors, as is currently the case for MA organizations, first provide an oral notice of an adverse standard coverage determination decision provided that they, then, subsequently issue a written follow-up notice of the decision within three calendar days of the oral notification.

We've also slightly modified our agent/broker training and testing requirements. All agents, whether they're employed or independent, are still required to receive annual training on Medicare rules, but we will now be requiring that that training and testing be conducted through a CMS-endorsed or approved vehicle.

Another provision that we got a great deal of comment on was with respect to our proposed rule requirement on translated marketing materials. As a result of consideration of those comments, we are finalizing a requirement that modifies the current standard in the Medicare marketing guidelines and will require that translated materials be provided for languages spoken by more than 5% of individuals in the service area for whom English is not the primary language. This means that the threshold will be calculated different than they were before in previous marketing guidance, and the focus will be on individuals who primarily speak a non-English language and have limited ability to read, write, speak, understand English and not on those who are at least by lingual as has previously been the case.

This rule also extends the grace period for good cause and reinstatement by finalizing its requirement in instances in which an individual was involuntarily disenrolled for failure to pay premiums timely during the grace period but who subsequently demonstrates good cause for failing to submit that premium timely.

Next, I'd like to focus on just a couple of provisions under the theme of requirements that strengthen our ability to approve strong applicants for the program, as well as to remove from the program poor performers. The first of these requirements is -- it's actually just a definition of what it means to be a fiscally sound operation, which is one that maintains at least a positive net worth. This is separate and apart from the state licensure and financial solvency requirements for an organization, which, as you know, are state specific, and they give up one more tool to sort of measure and monitor the financial health of the organizations we contract with.

We're also implementing a provision that would deny applications and service area expansion requests that are submitted by organizations that have less than 14 months experience operating their Medicare contracts. And, of course, we have a catch-all cleanup technical changes theme in our reg. There were seven provisions in this area in our final rule, and I'm going to focus on just three.

The first of these implements changes that would allow CMS to approve other enrollment mechanisms for cost plans, in addition to paper forms such as electronic enrollment. We've also made changes to the Part D transition requirements for a temporary supply of non-formulary drugs in long-term care settings, given the changes made to the program due to the long-term care waste Affordable Care Act provisions.

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And finally, we have modified the definition of dispensing fees, including what we consider to be reasonable costs. In part, to highlight the potential pharmacy costs aimed at reducing the volume of unused Part D drugs, and also to increase the efficiency of dispensing.

Okay. So that concludes my, as I said, high-level overview. I want to remind you that we expect to publish the rule in the Federal Register later this week. Right now there is a link to the version that displayed at the Office of the Federal Register and online at their site on our health plans web page, the link that's provided on this slide. We will, of course, update that link with the PDF that represents the version that publishes in the Federal Register later this week.

I also want to make sure that you have plenty of contact information at the staff level for any general questions you may have about the rule but also Part C, Part D, payment, and enrollment and appeals questions. And with that, I think Jill is going to take over to help moderate the Q&A session. Thank you.

Jill: All right. Now all you have to do is raise your hand. We have people with lights, because oddly enough, it's very hard to see from up here. And then if you have a question for one of our specific panelists, if you could please address them by name, or if it's for the good of the group, that's fine too. So put your hand up in the air, we'll get a microphone to you. Don't be shy. And we have a question. Do we have one over here or back here? Okay. Could you please identify yourself?

[Audience Member's Name Withheld]: Sure. My name is [Audience Member's Name Withheld]. I'm from [Organization Name Withheld]. My question is about the disenrollment for failure to pay premium and that we can reinstate them for good cause. Our health plan currently does disenroll for failure to pay premiums, and we get a lot of requests for reinstatement, and I wondered if CMS was going to give more clear guidance on what's considered good cause, because the number of reasons that we hear -- I mean it's the full gamut of why they didn't pay. So, you know, what could be good cause to one person may not be to another.

CMS Panelist: Thank you so much for your question. Yes, CMS will definitely be putting out additional guidance. We're working on updating our chapters regarding enrollment policy, which also includes, as you well aware, disenrollment policy. So we will be outlining what constitutes the parameters of good cause. Certainly, it would be very limited, and we would be providing that with our updates in the coming months.

Jill: We have another question.

Audience Question: Yes, hi. My name is [Audience Member's Name Withheld]. My question is to Vanessa, I believe. The agents' training that you mentioned where CMS is going to implement something that CMS approved, is that going to be effective for AEP 2012?

CMS Panelist: No. I think because of the timing of the release of the rule we don't have time to really look at proposals and approve or endorse training programs for 2012. So I think we stated in the preambles of rules that it is our intent to probably delay this until 2013.

Audience Question: Okay. Thank you.

CMS Panelist: We have a question over here

Audience Question: Yes, my name is [Audience Member's Name Withheld] from [Organization Name Withheld], and I have a question about the 5% marketing materials in the foreign language. How is that going to be calculated? Are we going to be given the percentage in our area, and does that also apply to the website?

CMS Panelist: We provide resources to help you identify what languages should be covered in, I think it's the HPMS.

Jill: Another question up front.

Audience Question: Hi. Hello? Okay. Cool. Hi, it's [Audience Member's Name Withheld] from [Organization Name Withheld], and I have a question specifically related to the uniform appeals process for coverage determinations. We submitted a request, or at least a comment, to 4144 because their organizations contract with different companies to do coverage determinations for the organization that does the appeals, and so having not seen what the final version looks like, is the expectation that, for example, the online request for members to ask for a coverage determination has to be

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organized through the same portal or system, or is there some allowance for a non-uniformity in the actual business relationships?

CMS Panelist: In the final rule we received a comment about the web-based interface. And due to the number of comments we received in the final rule, we have allowed for a lesser requirement that we believe will be much less burdensome to plans. So in the final rule we have set a minimum that plans must be able to take -- or enrollees must be able to request a coverage determination via secure e-mail on the plan's website and that e-mail must be prominently displayed on your website, and then we have allowed for the opportunity for plans who are more technologically advanced to proceed with implementing a web-based portal for, you know, enrollees to request a coverage determination. But for right now you can proceed with secure e-mail.

Jill: Are there any other questions? Yes, we're pointing in the back. Okay. We have one.

Audience Question: [Audience Member's Name Withheld], [Organization Name Withheld]. In terms of the 14 months in order to be able to file a new application or service area expansion, is that at the plan level, the parent level, the contract level?

CMS Panelist: It's at the legal N&D level. It's the whole organization. You just got a team answer.

Audience Question: Parent level then or legal entity?

CMS Panelist: Legal entity.

Audience Question: Okay.

Jill: Are there any other questions? Any in the back, wave high? Yes, we do. Go ahead.

Audience Question: Hi, [Audience Member's Name Withheld] from [Organization Name Withheld]. With respect to the limited English proficiency requirements, is there any plan at CMS to start to release model communications in languages other than English?

CMS Panelist: It's something that we're considering, creating some model language is for plans and sponsors to use.

Jill: All right. We have another question over here.

Audience Question: Hi, I'm [Audience Member's Name Withheld], [Organization Name Withheld], and I actually had two questions. One is about the physician reviewing initial determinations. Does that include coverage decisions with drugs? So a pharmacist would not be sufficient?

CMS Panelist: Well, what we say in the rule is that it has to be a physician or appropriate health-care professional.

Audience Question: Oh, excellent. And then the other question was on the prohibition of participation by plans whose owners or directors serve in a similar capacity that terminated a contract with prior plans, owners, and directors means what exactly?

CMS Panelist: Owners and directors have a 5% or more stake in the company.

Audience Question: So if it's a non-profit, that wouldn't really apply, which we're not owned?

CMS Panelist: I guess we'd have to see the specific details behind it.

[Audience Member's Name Withheld] Okay.

CMS Panelist: But probably not.

[Audience Member's Name Withheld]: And would that apply to existing plans? So, say, we did have an owner and they -- two years ago were in a plan that terminated, we have to fire them?

[LAUGHTER]

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CMS Panelist: Okay. We're crafting the answer.

[Audience Member's Name Withheld]: Sorry, I just can't stay off the stage apparently. For that particular provision, if we're speaking specifically to members of the board of directors or owners in appropriate cases that have made a decision, that have been part of the decision to leave the Medicare program, and what we are trying to avoid is for those specific individuals to have made that decision, along with their colleagues, to leave the program and then immediately form a different corporation to come back in or be part of another corporation but that then comes into the program. Because we also have a two-year exclusion that we've had for quite a long time about when an organization leaves the year date and they have two years before they can come back in or just adding to that the definition that it also applies to individuals who have been part of making that decision. Okay. So if we get a new board member that meets that, we'd have to -- you're expecting us to screen for that.

CMS Panelist: I'm sorry. Yes, potentially so.

[Audience Member's Name Withheld]: Okay.

CMS Panelist: All right. Thank you, [Audience Member's Name Withheld]. I wondered if we'd see you. Good morning.

Jill: Anyone else. One more question.

[Audience Member's Name Withheld] with [Organization Name Withheld]. This won't be quite so difficult. Are you setting limits on your maximum dispensing fee within those regulations for pharmacy?

CMS Panelist: No, we're not setting a maximum dispensing fee.

Jill: And do we have one more question in the back? Yes?

Audience Question: Hi, [Audience Member's Name Withheld] from [Organization Name Withheld]. I just have a quick question on whether or not CMS is going to be moving towards the summary of benefits under ACA, the four-page that's a part of it? We haven't heard anything, if we're going to have to abide by that.

CMS Panelist: That provision applies to, you know, private health plans. I don't think it's intended, at this point, to change our current summary of benefits.

And I can also for clarification on a previous question about the 5% marketing material threshold for translation. We currently provide that information at the plan level in HPMS, as Chris said, and we will be recalculating that at the 5% level. As Vanessa already spoke about, we're going to be focusing on population of individuals who are not bilingual. Our current data does capture some of those. So, in essence, the effect on you all as planned is going to be very minimal because our calculations are showed that essentially the language and number of organizations that will need to translate is not very different from what it is today at the 10% level, and we will be providing that at the plan service level as we currently do.