2015 Medicare Advantage and Prescription Drug Plan Spring Conference & Webcast Transcript

2016 Policy and Technical Changes to the Drug Benefit Program

All right, our next presenter is going to discuss the 2016 Policy and Technical Changes to the Drug Benefit Program, Lieutenant Marie Manteuffel.

Good morning and thank you for everyone joining us, both in the room and virtually online today. I'm Lieutenant Marie Manteuffel. I am a pharmacist with the U.S. Public Health Service, serving at CMS in the Division of Part D policy. And as mentioned, we're going to go through the rule that was just published this February.

So the agenda for my session is pretty straightforward. It's really just going to walk through, in 28 minutes or less, the provisions that were in the February rule, a little bit of history and background to that rule being published, and a brief synopsis within the rule, and then if there's time at the end, some Q&A.

So, just as background, we published a notice of proposed rulemaking back in January of 2014, so last January, which had a number of proposals for both the C and D programs. This was available for review and for public comments. And after that, that January posting, there was a final rule issued last May, May 23rd, 2014, which finalized some of the proposals, and then today we're talking about the final rule published this February, so February 12th 2015, which finalized additional proposals from that January NPRM.

Back to the Top

So just kind of looking at some key dates and the timeline going forward, as noted, the rule itself, the second final rule published February 12th, 2015, the CFR, Code of Federal Regulations, effective date or when it gets into the CFR, was about a month after that, so March 16th of this year, and the CMS applicable date or when these provisions more so are applied or the contract year, we're looking these to be applied to is contract 2016, so, really, the applicable date of January 1, 2016. There are a few exceptions to this. Those are noted in the rule itself. But by and large, all of the provisions -- most of the provisions within the final rule are going to be applicable January 1st of next year.

And, actually, before I go back, I'll just note too, on this, just to point out that NPRM that was published in January 2014, the title of that rule does say "Contract year 2015." But just to be abundantly clear, the title of the February rule, this year, does say "Contract year 2016." So when these were proposed, it looks like 2015, but anything published this February, as noted in the title, you will see is for contract year 2016.

With that, we'll start to walk through some of the provisions that are in the regulations. Generally, they fall into five different buckets. You see those listed here. We're just going to go through these in order, with one bullet for each provision under these categories, and these headings align with the section headings that you see in the final rule. The final rule in its complete form is available online. It can be downloaded or printed as well, but you'll see that we're just kind of going in order and aligning with that.

Looking ahead, you'll see the fifth bullet and other technical changes catch all buckets, but you'll see as we go forward, too, that some of the provisions falling in buckets one through four are also pretty small technical changes as well. So we'll see those as we go through them. So to dive in, the first provision, talking about changes to audit and inspections authority, this change added the word "timely" before our audit and inspection authority to match the wording of the statute, so change there. This change also allowed CMS to require Medicaid advantage organizations or Part D sponsors to hire an independent auditor to validate the correction of CMS audit findings.

The next provision discusses enrollment eligibility. It establishes lawful presence for U.S. citizenship as eligible criteria for enrollment in Cost, MA, Medicare advantage, or part D plans. This rule also codifies that beneficiaries must have U.S. citizenship or be lawfully present in the United States, as outlined in 8 CFR 1.3, to be eligible for enrollment in Cost, Medicare Advantage, or Part D plans. Beneficiaries are not eligible for enrollment and will not be able to enroll in or remain enrolled in these plans. And on this topic specifically, there will be more information in an afternoon session today.

Back to the Top

The next provision is talking about the Part D notice of changes. This change codified for Part D language found in the Part C regulation, requiring that MA organizations and Part D sponsors provide an annual notice of changes to their plan rules to CMS for our marketing materials review, and to all enrollees at least 15 days prior to the annual coordinated election period for changes effective the new plan year. It also states that notices for other changes must be provided consistent with existing requirements in 423.

The next provision discusses business continuity plans. This requires MA organizations and Part D sponsors to develop, maintain, and implement business continuity plans meeting certain minimum standards. The final provision was modified due to public comments that we received, and it will now require that MA organizations and Part D sponsors plan to restore essential operations within 72, not 24, hours of a failure.

The next provision discusses the revisions to the rule requiring efficient dispensing to Part D enrollees in the long-term care settings. This does this by a number of different ways. One is through adding a prohibition on payment arrangements that penalize the offering and adoption of more efficient dispensing techniques by prorating dispensing fees based on days supplied, or quantity dispensed. It additionally adds a requirement that any difference in payment methodology incentivizes more efficient dispensing techniques, and lastly, it did eliminate language that has been misinterpreted as requiring the proration of dispensing fees.

The next provision is discussing employer group waiver plans or EGWPs. This is finalizes the small portion of the provision that requires Part D sponsors offering employer group waiver plans to provide applicable discounts to EGWP enrollees, as determined consistent with the defined standard definition.

The next provision discussing TrOOP or True Out-Of-Pocket costs, talking about the transfer of TrOOP between PDP sponsors due to enrollment changes during the coverage year. This change requires Part D sponsors to report benefit accumulator data in real time, except real-time data reported by any prior plans in which the beneficiary was enrolled for that paid claims on the beneficiary's behalf during the coverage year and to apply these costs promptly.

The next provision discussing quality improvement programs, this revises 422.152(a) to codify recent expansion of the quality improvement program policies, and it also revises 422.152(c) to codify recent expansion of chronic care improvement program policies. Specifically, 422.152(a) reinforces the requirements as 422.152(c) and (d), which state that MAOs conduct quality improvement projects and chronic care improvement programs for each of their plans on an annual basis. 422.152(c) has been updated to accurately reflect what MAOs are to include in their CCIP.

Back to the Top

So that kind of walks through the provisions that were in that first bucket. Those were all the provisions clarifying various program participation requirements. Moving on to the second bucket, these are the changes in the final rule discussing improved payment accuracy. So five separate provisions kind of falling under this category. The first proposes a technical change to 423.329(d) to correctly describe the low-income cost-sharing subsidy payment amount as it is intended by statute and has been implemented and described and interpretive guidance by CMS.

The second provision amends the provision to accommodate reopening of the coverage gap discount reconciliation. The third item revises 423.350 to accommodate a coverage gap discount reconciliation field process. The fourth adds a new paragraph to 423.2320 to describe a process for accounting for quarterly invoice amounts that go under paid by a bankrupt manufacturer. And the final provision in this category is talking about risk adjustment data requirements, and this change revises the regulations to allow CMS to establish an annual deadline for final risk adjustment data submission for a payment year to allow for operational flexibility and clarifies that CMS will never set a deadline earlier than the current deadline of January 31st.

So those were the five provisions falling in the second category. Moving on to the third category, we're looking at provisions finalized that strengthen beneficiary protection. The first provision is about MAPD coordination. This change requires MAPDs to establish and maintain a process to ensure timely and accurate point-of-sale transactions. This includes adequate messaging and other procedures with network pharmacies to ensure care continuity and coordination at the point of sale between Part D drug benefits and Part A and B drug benefits administered by the MAPDs.

The next provision is good cause processes. This established the authority for CMS to assign plans to review and process good cause requests on its behalf. This regulation permits CMS to assign an entity, such as an MA organization, Part D sponsor, or an entity offering a cost plan to act on its behalf to review good-cause requests following involuntary disenrollment for nonpayment of premium and effectuate reinstatements of beneficiary enrollment when criteria are met. There will be additional information on this topic as well during the afternoon session.

The next provision is also talking about MA organizations, and this change made revisions to regulatory language related to when an MAO can invoke an extension of the adjudication timeframes for organizational determinations and reconsiderations. As you can see on the slide, these changes clarify our intent to assist plans in properly limiting use of extensions by providing these three specific requirements. As you can see, they must be in the interest of the enrollee, they are limited to extraordinary circumstances, clarifications, that extensions should not be used when the plan is requesting clinical documentation from contract providers. So those were the third category.

Back to the Top

Moving on to the fourth category of provisions in the final rule, these are those changes discussing strengthening our ability to distinguish stronger applicants to the Part C and D program participation, and this has three provisions falling underneath it. The first is the two-year prohibition when organizations terminate their contracts. So this amends text to explicitly apply the two-year prohibition to applications for service area expansions, in addition to applications for new contracts. It also adds language to clarify that a mutual termination of an MA contract would result in a ban of all contract types and service area expansions.

The next proposal, with some background, CMS in making certain that all organizations that are submitting an application for standalone prescription doctoring plan contracts do so in good faith, with a sincere interest in delivers Part C benefits to all beneficiaries not just LIS beneficiaries enrolled through the auto assignment process. To address the issue, CMS, here, has adopted a penalty to discourage new applicants with a business model based on solely having bids that qualify for auto-enrollment. So specifically what this does is imposes a two-year Part D application ban on organizations approved by CMS as qualified to enter into standalone PDP sponsor organization contracts but which elect, after our announcement of the LIS benchmark, not to enter into such contracts and withdraw their PDP bids.

The next provision is discussing a new essential operations test requirement for Part D. This creates a new step in essential operations test in the application and contracting process with newly contracted entities operating as standalone PDP sponsors or MA organizations offering Part D plans.

So that takes us to kind of the fifth bucket, the final bucket of other technical changes. Some of these are very, very minor, things like cross-reference changes and things like that, but just to pull out a few of the items from this section, looking at the second bullet, so agent and broker training and testing requirements, this change removed the requirement that agents and brokers be trained with CMS-endorsed or approved documents. It still requires that agents and brokers be trained and tested annually.

Another item from this section, the second to last bullet, the managing, disclosure, and recusal in P&T conflicts of interest. This change requires the sponsors pharmacy and therapeutics committee to clearly articulate and document processes to determine that certain requirements have been met, including determination by an objective party of whether disclosed financial interest are conflicts of interest and management of any recusal due to conflict.

So this slide has the remaining technical changes that were included in the final rule. To discuss just a few of these, the third bullet, the MA organization responsibilities and disasters and emergencies, this change codifies and further clarifies an MA organization's responsibilities when health plan services are affected by public health emergencies or disasters. And the final item the, final bullet listed here regarding restrictions on use of information under Part D, this is just a technical change to align with the Affordable Care Act Amendment Section 18, as well as other sections of the statute.

Back to the Top

So listed here are some key contacts that were listed in the final rule as well. The provisions included in the February final rule represent various different divisions and groups within CMS. So we have various groups and contacts here that you can reach out to. In addition, there was also, I believe, a SurveyMonkey link sent to everyone participating online. So questions submitted there can also come in and be triaged at that point.

With that, that concludes my prepared remarks. I'm happy to address any questions as well. Thank you.

All right, we now have an opportunity for Q&A, which means that if anyone from our in-house audience has a question, if you'd please step up to the microphone that is in the center aisle and you will have an opportunity to ask your question. And if there are know questions from our in-house audience, then I would like to go ahead and ask a question that was sent in from one of our viewers. And that question is, "Why has CMS stopped posting the actual March, September, and January sweeps dates?"

That's a great question. Those were dates that used to be posted in the call letter, and started in calendar year 2014, those are now sent through a memo through HPMS search year. We will send the dates for the coming year in the next few weeks, and we are aligning the deadlines with the sweep dates so that they're now one in the same. So that is a change, so thank you for pointing that out.

Question?

Hi. Good morning.

Good morning.

Steve Novis, Glaxo Smith Kline Pharmaceutical. The proposed recommendations to impose new requirements for outreach strategies related to medication therapy management have not been finalized by CMS. Can you provide any insight into the work that CMI, CMMI, and CMS are engaged with respect to MTM, and when an update might be provided.

Okay, so I believe you're asking a proposal that was included in the January NPRM, so January 2014 regarding MTM. At this point, really all I can say is sort of what's finalized is finalized. There were certain provisions that we've stated publicly we would not finalize without first re-proposing, and those we certainly would not finalize without re-proposing first. But regarding any other coming changes, I'm not aware of anything at this time.

Okay, thank you.

Yeah.

Back to the Top

Okay, thank you for your question. And one thing I did forget to mention, and this gentlemen did do it, is if you do come up to the mic in the center of the room, if you could please tell us who you are and where you're from, that is helpful too.

So I do have another question from a viewer, and that question is, "As part of CMS's record retention policy, it states 'ten years.' Please clarify that the ten-year requirement still applies."

Okay. So I don't know that that's necessarily specific to any one provision within the rule that we're discussing, but just kind of as a general rule, yes, there is a ten-year document retention requirement that is in regulation at 423.505(e)(4), so that is correct.

Okay, are there any additional questions out there? Okay. Well at this time, I would like to thank Lieutenant Manteuffel. And we will go ahead and do our evaluations. Thank you.

Back to the Top