Prescription Drugs Events, Formulary Issues, and Part D Compliance

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Angela Stanley: Okay. Again, my name is Angela Stanley. I work in the Division of Payment Reconciliation in the Medicare Plan Payment Group. So, obviously, my job today is to give you an overview of how CMS makes Part D payment reconciliation payments to plans, how do we collect the data, what do we use the data for when we get it in house in ways that can be beneficial to you as PACE organizations. I'll go through what our expectations are in interacting with us as we do data analysis and share that information to you, what your responsibilities are as a plan in providing updates to PDE data and responses back to CMS.

And then, finally, I'll talk about, you know, sort of the reason why we do all of this, why do we do -- why do we edit PDE data, why do we collect it in the first place, why do we spend all of our time and resources, ask you to do the same, and that's to provide the most complete and correct PDE data, which is one of the primary sources of data inputs into Part D payment reconciliation. That's how much we know you actually spend on prescription drugs for Medicare beneficiaries.

So, again, we're going to just do a brief overview on what the PDE submission requirements are, not necessarily the technical requirements, but timing; how frequently you should be submitting, when you learn of errors, what does that mean in terms of making corrections to your PDE

data. Then we'll get into what does CMS do with the data and what you guys should do in response. And then, finally, we will discuss the Part D payment reconciliation activities. I'll give you just a very high level timeline of when activities for reconciliation occur. They generally occur on the same schedule every year, so this is another thing that you may want to print and post on your desk, just so you aren't surprised when these deadlines come up every year.

Okay. So, as far as PDE submission requirements go, all Part D plans, including PACE organizations, are required to submit original PDE claims within 30 days of the date of service, or when the claim was received, whichever is later. If you are notified that a PDE was rejected or you are aware, through your own data analysis, that an error in PDE reporting has occurred, you have 90 days from when you learn of the error in order to submit adjustments and deletions into the system.

These PDE submission timeliness standards have been in place for a number of years, since October 6th, 2011, and we do monitor these activities -- these submission timeliness standards on a quarterly basis. We have a process in place where if organizations are not meeting these standards, we do technical assistance outreach calls. If we notice a continued pattern where plans are failing to meet these timeliness standards, we do issue compliance actions. And, unfortunately, we've noticed that PACE organizations are often the recipients of these compliance notices.

So, we do realize that it's the PBMs that often submit this data on behalf of PACE organizations. So, if you find that you are getting these compliance notices for timely submission, you may want to work with your PBM to sort of up the schedule of submissions. Instead of once a month, try once every two weeks. And we've seen, over time, as organizations have upped their submission habits to once every two weeks, that their

likelihood of hitting any of these timeliness standards has gone down dramatically. So, that's a suggestion to take back if you find that you are getting these compliance notices.

Once we get the PDE data in, we have several ways -- several types of reports that CMS generates and shares with all Part D organizations, including PACE plans. The first set of reports that I'm going to go through we actually post via a contractor that we use on the PDE Analysis of Reports website. The memo that's listed at the bottom of this slide gives information, if you're not familiar with the website, for where to go to request access and to make sure you or someone in your organization is able to access these reports, and to make sure you have a process to take action on these reports. Some of the reports, there are two sets of reports, the immediately actionable PDE error report and the eligibility error reports, that don't require any response back through the data analysis website, however we do expect that plans follow the timeliness standards that we just discussed in order to submit corrections to the PDE data.

There is one more type of report that's posted to the PDE analysis website that's not listed on this slide, and it is the Part D Payment Reconciliation Data Quality Report. And this report basically takes PDE data across a beneficiary rather than, you know, how when we take intake PDE data, we usually edit it at a line level. So, we aggregate PDE data at a beneficiary level and we can tell certain -- we can identify certain errors that may be problematic with, you know, TrOOP accumulation or benefit administration, those types of things. And so, with that report, we do expect that plans research those heavily and respond in two ways, either if there are corrections to be made, that the PDEs are updated according to the time schedule we discussed, but if the plan believes that those PDEs are valid, then there is a response form that needs to be completed through the PDE analysis website.

And, again, we've observed that PACE organizations tend to be -- represent the plans that are non-responsive to these analyses that are posted. This is something that we track. It's something we take seriously because the PDE data, again, is the way that you tell us what your Part D costs are. We think these are valuable tools for organizations to have a process in place to make sure that what you have on record as your Part D drug spend is the same that CMS also has on record. So, again, if you're not familiar with these reports, check out the memo that was listed a couple slides ago, and get yourself signed up for those.

The next set of reports that CMS generates for the benefit of plans are PDE monthly reports, and these reports are distributed through the Drug Data Processing System. And, again, we just ask that PACE organizations, like all other Part D sponsors, have a process in place for receiving these reports and doing some accounting between the amounts that are displaying on these reports versus what you have in your own internal system.

The first one of these reports comes from the Prescription Drug Front-End System. It's a -- it's called the PDFS Response Report. This is the first indication of if your PDE file was accepted by CMS. If you get a PDFS response report that says that file was rejected, then none of the PDEs contained in that file are saved to CMS' database.

The next report that's issued by the system is the Cumulative Beneficiary Summary Report. It provides summary of accumulated totals at a beneficiary level for all of the dollar-amount fields. One of these reports is issued per benefit year. And the report breaks out by contract and PBP. And, again, use that to compare against your own internal systems.

Another report is the Part D Payment Reconciliation Report, and, again, this is an even higher level. It's the year-to-date cumulative report for the contract of record for all of the financial amounts reported by your submitted contracts for use in the Part D Payment Reconciliation. And this is distributed monthly. Finally, we issue a plan-to-plan payable report every month. And it is -- this serves as the invoice to the contract of record showing how much is payable to each of the submitting contracts.

Okay. So, what is the point then of spending so much time ensuring that PDE data is accepted by CMS, that it's complete and correct, and, you know, of course the point is accurate Part D payment reconciliation. You heard Amando talk about this is, like, the exact information that they're auditing when they come for one-third audits. And so, you know, we want it to be correct because we want to make sure we're paying reconciliation based on complete and accurate data. Other organizations with a more compliance and internal control bent also are looking at this information. And so that's -- so, the PDE data is one input into the Part D payment reconciliation process.

We do gather other information about enrollment and we get information about how much money was paid to the plans prospectively. The other source of information we gather, that you heard Amando mention, is the Direct and Indirect Remuneration data. That data is collected via HPMS. And, again, this primarily represents the manufacturer rebate data. And PACE organizations are unique in that some organizations do participate in manufacturer rebates while others opt not to. And so we have accommodations for PACE organizations that choose not to participate in manufacturer rebates, and so we'll talk about, in the next few slides, about how we accommodate those.

So, in the DIR submission process, which, again, happens via a module in HPMS, there are three parts that encompass a complete DIR

submission. First, organizations have to submit a DIR Submission Information, and that's sort of like, you know, the gate that you have to go through before you can even upload any of your rebate data into the system. And so -- and I did just want to mention that we're currently, now in the open window, accepting DIR information for the 2016 Part D payment reconciliation year, as well as data for 2015 and prior through 2012 prior years to provide CMS annual updates to that information. The deadline for that is July 31st. So, if your organization is surprised by this, now is a good time to touch base with the memo, and I'll give you some resources for organizations and people within CMS that you can contact for help.

So, again, we realize not all PACE organizations participate in manufacturer rebates, and thus would not have DIR to report. However, if this is the case for your organization, there are still a few things that you have to do. Again, remember, I said there are three steps, the submission information, the summary DIR data, and the detailed DIR data. So, if you don't have -- if you don't participate in rebates, you still must submit the DIR submission information, and there's certain information that you can indicate that you don't participate in rebates in that section. And then you must submit a summary DIR report indicating that your total DIR is zero. And you guys are not required to submit a detailed DIR report if you do not have any DIR to report on the summary.

This slide basically goes over some specifics within the DIR submission information section that allows PACE organizations that do not receive rebates to indicate that. Again, this is another place where PACE organizations disproportionately represent organizations that are non-responders to the annual submission of DIR data. They require a lot of outreach on our behalf in order to collect this data from organizations. So, in order to assist plans, PACE organizations and traditional Part D plans,

we have Helpful Hints documents available for each file that needs to be uploaded.

And so my suggestion is that you attempt the upload early and often. And if you run into any issues, there are contact emails and phone numbers within these Helpful Hints documents. And I'll also provide a contact email at the end of my presentation. And please, please reach out to us if you're having issues with getting your files uploaded and we'll be happy to help. I'd actually prefer to help now than after the deadline has passed. So, please, please reach out.

So, if you believe that you've successfully uploaded your DIR information and you just want to confirm that what you thought you uploaded is in there, or if you uploaded, you found an error, you needed to re-upload a file, and you want to make sure we have the correct version, this slide gives you a walk-through about how you can go about seeing exactly what DIR data report is saved and will be used for payment reconciliation.

The final step in getting to a Part D payment reconciliation payment or recovery to the plans is a series of annual attestations. And, again, there are a total of three attestations that must be completed prior to Part D plans, including PACE organizations receiving the money from CMS. And these include the attestation of data related to CMS payment to a Medicare Part D sponsor, attestation of data related to detailed DIR report, and a record and attestation of plan-to-plan reconciliation payments. And, again, Part D reconciliation settlement will not be made if attestations are not received.

So, the attestation of data relating to the detailed DIR report does have a caveat with respect to PACE organizations that do not participate in manufacturer rebates, and thus have no DIR to report. They -- these organizations are exempt from submitting the detailed DIR report, and, of

course, then the attestation associated with the detailed DIR report. And just keep in mind, though, that even if PACE organizations do not have DIR to report, an attestation must be submitted for the summary DIR data, which you would have indicated as zero -- so, you need to attest to that -- and for the plan-to-plan reconciliation payments.

Again, this is the timeline I mentioned that just sort of walks through the information collection and how we use the information working up to issuing Part D payment reconciliations. And I will just tell you that on the second bullet of this slide, we say -- excuse me, the third bullet, the DIR submission window is typically in the month of June. This year, we did have a delay in issuing the final DIR submission guidance. So, this is actually the end of July, July 31st is the deadline for submitting DIR data for this year.

So, I wanted to provide a few very good information resources for both PDE submission and timeliness and accuracy, as well as information for payment reconciliation. So, HPMS, you've heard us talk about it before, if you're not in there, you should be in there daily. There's also the CSSC Operations website and the PDE resource email mailbox, which I'll give you.

So, in HPMS, as you guys are aware, the policy and operational guidance memos are issued through HPMS. Often, when we receive questions from the plans, we can tell if organizations haven't consulted the HPMS and haven't read the memos. And so we just beg that plans make sure you're consulting HPMS, use the search function to pull up all relevant memos, and just use that as a very first resource for answering questions. And, again, within the DIR module, we do have the memos posted, plus additional helpful hints documents to help you get your files uploaded.

HPMS also has many administrative and reporting functions. You've heard some from Amando. We use it through -- to collect DIR data. HPMS manages an email distribution list and points of contact that we may pull for email distribution. So, for example, we have a specific DIR contact. So, just make sure that you are constantly updating the points of contact that you have listed so the correct people in your organization get notified of the information that they need. If you're not an official point of contact for your organization, but you do wish to receive the emails that come out from HPMS, there's instructions on how to do that, too.

The CSSC Operations website is listed here. You can select PDE from the sidebar menu, and that will provide you all of the updated file layouts, edits, system status reports. There's just a ton of information on training on how PDEs are calculated, how PDEs are to be reported. There are computer-based training modules on some complicated PDE calculation questions that we've gotten in the past from Part D sponsors. Additionally, CSSC also has their own website at -- or listserv on their website, and we encourage everyone to sign up for that if you have not already.

And, finally, if you've exhausted both the CSSC website and HPMS, and the wealth of information that's stored in the HPMS memos, there is a PDEJan2011@cms.hhs.gov resource box. And so any and all questions that are PDE submission, data quality, timeliness, how it gets fed into Part D reconciliation, DIR, all of those types of questions, so basically everything -- every topic that I've covered in my presentation, we have subject matter experts from my division that monitor that mailbox on a daily basis and would be happy to help work through your question and point you to the correct resource.

Teddy Pitaktigul: Thank you, Angela. Hello everyone. My name is Teddy Pitaktigul and I work in the Division of Formulary and Benefit Operations. Today, I'm going to talk to you about Part D formularies. First, I'll go over the

background of Part D formularies, then how CMS reviews these formularies, and what's expected of sponsors when they develop their formulary, and, lastly, how this applies to PACE organizations.

So, I'll start off with the background of Part D formularies. As described in the Medicare Prescription Drug Improvement and Modernization Act of 2003, CMS cannot mandate a national formulary. However, CMS has exercised its antidiscrimination authority to ensure that formularies are not discouraging enrollment of eligible Part D individuals. And in the beginning of the program there was no template publically or previously available by the private sector, so, because of their review of the Part D sponsor's formularies, CMS had to develop this new process for reviewing these formularies. So, to ensure that beneficiaries were not discouraged for enrollment, Part D formulary submissions must be reviewed and approved prior to bid approval.

CMS receives hundreds of formularies for review each year. The initial formularies are submitted in the summer, before the beginning of the contract year. And due to the volume of submissions and review timelines, a standardized process must be -- a standardized process is essential for this. And because of the standardized process, CMS requires that formularies be submitted on a website called HPMS that was mentioned before. This website holds the different tools that allows CMS to communicate with the plan sponsors and allows for the standardization of the submission format, as previously mentioned. Sorry.

Submissions are also based on the Formulary Reference File, or FRF for short. And I'll talk more about the FRF in the next slide. And reviews are usually conducted during the summer. The drug list and the associate utilization management requirements, such as prior authorizations, step therapies, as well as plan-submitted tiering are reviewed in three stages. After each review stage, Part D sponsors can provide a clinical

justification or they can revise their submissions, or do both. And the final stage of the review involves addressing any unresolved issues, formulary negotiations, and conditional approvals.

So, I want to go back to talking about the FRF. The FRF includes RXCUIs. These are adopted from the National Library of Medicine, or NLM for short, their RxNorm classification system. This classification system has distinct brand names, generic names, strengths, routes of administration, and dosage form of drugs. The FRF serves as a pick-list for drugs for the formulary inclusion, and it allows streamlined processes and reviews, as well as improved synchronization between CMS and Medicare plan finder files. But one thing to note is that the FRF is not a coverage list for Part D drugs. In other words, the medications on the FRF are not a strict list that plan sponsors must cover.

I'll briefly talk about sponsors and how they develop their formularies. In addition to adhering to CMS guidance regarding formulary construction, it is CMS' expectation that Part D sponsors have a P&T committee, a pharmacy and therapeutic committee, that develops and reviews these formularies. The P&T committee must also review all the utilization management applied to drugs, such as prior authorization, step therapy, and quantity limits.

So, how does this affect PACE organizations? In the Medicare Modernization Act of 2003, it states that PACE programs must provide all Medicare and Medicaid covered services, as well as state Medicaid programs may no longer cover Part D drugs on the behalf of dual-eligible beneficiaries. So, since PACE organizations must provide all services, this includes all Part D drugs, generally they're waived from having a formulary. PACE organizations may elect to offer a Part D plan similar to an MA-PD local plan in order to account for the shift in payments, as mentioned in the previous slide, but once they choose to offer a Part D

plan, they are subject to all the rules and regulations that are acted upon a Part D sponsor.

If a PACE organization does not cover a certain medication, a certain Part D medication, or has any limitations such as prior authorization, step therapy, quantity limits, the organization is then deemed to be utilizing a formulary. And once a PACE organization is deemed to be using a formulary, that formulary must be submitted to CMS for review and approval in the same process that is followed by all Part D sponsors.

And I want to end my section with a polling question to see if you -- see whether you guys think that this PACE organization should submit the formulary to CMS. And the question is a PACE organization has rejected the coverage of a Part D drug because the patient has not tried and failed a preferred drug first. Is this PACE organization subject to the rules and regulation of a Part D formulary? Enter A for yes and B for no. And we'll wait for the results to come in, but we shouldn't wait too long.

So, the results are coming in. And it looks like the "Yes" column is fluctuating. It looks like it's steady right now, so 92 percent of the people voted yes for -- that the PACE program should submit their formulary. And the answer is yes, they should. This PACE program -- this PACE organization is deemed to be using a formulary that is similar to a step therapy requirement. And since they are utilizing a formulary, they are subject to all the rules and regulations that a Part D sponsor has. Their formulary should be submitted via HPMS, and reviewed and approved before implementation.

And I'll end with the last slide that I have. This is a Part D formulary mailbox. You can submit all formulary-related questions to this mailbox and it will be answered by a subject matter expert. With that, I'll turn it over to Jasmine.

Jasmine Myers-Duncan: Thank you, Teddy. And thank you, Angela. I'm Jasmine Myers-Duncan in the Medicare Drug Benefit and C & D Data Group. I will be giving a brief overview of the types of compliance that some of you have encountered or could potentially encounter in your operations as a PACE organization. First, I would like to offer that PACE compliance can come from your account manager or it comes from the central office, which is our division. And also note that any compliance you receive is separate from regular communications that we -- that you may have with your account manager. We encourage regular communication with your account managers there on the ground with you. Feel free also to always contact us here at central office, but just know that the communications that you may receive in the form of a compliance letter is separate from that regular communication.

I do want to differentiate some things that you may have heard in session one in the audit process regarding compliance because some of the vocabulary is the same, but there are some nuances involved. The compliance that I will be discussing is monitoring compliance. It's episodic, data-driven analysis that the C&D Data Group conducts, which is different from the ongoing comprehensive program audits that you were reviewing in session one.

Compliance from our group typically is closer to real time, and by that we mean when we issue compliance, more likely than not, it has happened in recent times whereas the program audits are done retroactively. So, it may be a finding that was something that happened in a previous year, whatever that time period is prior to receiving that engagement letter from the audit committee. And also our compliance may also include some ad hoc issues that may come to our attention through complaints, through the account manager, through self-disclosure.

So, the first type of notice -- first type of compliance you may receive is the notice of non-compliance. This is the most basic form of compliance that you may receive. It's often issued for a relatively minor regulatory noncompliance. It's to inform you that you are out of compliance, that we are taking note of this. It also puts you on notice that it has happened. And hopefully, from there, the plan will take steps to remediate whatever that issue was.

The second type of notice you may receive is the warning letter. It's an escalated version of the notice of noncompliance. It generally pertains to an issue to which you may have already received a notice of noncompliance or it can be issued prior to receiving a notice of noncompliance, meaning depending on the severity of the issue at hand, the type of noncompliance, you may receive a warning letter and not actually receive a notice of noncompliance.

There's also a warning letter with the request for a business plan. It's the same type of notice as the warning letter, however CMS is asking for you to submit to us a workable, a real plan to implement within your PACE organization to remediate whatever caused the noncompliance. So, this instance, we're asking you for a business plan. There may have been great beneficiary impact with whatever the noncompliance was. So, we want to make sure that it does not continue and that you have the ability to take the steps to correct that action.

Finally, there's the Corrective Action Plan. This is the highest notice that we would issue before referring for an enforcement action, a sanction, or a CMP. Typically, a CAP comes from multiple notices of noncompliance or warning letters having already been issued, and the underlying issue has not been resolved. This, too, can be issued initially for a particularly egregious violation of CMS regulations and/or the PACE program agreement.

Throughout our entire compliance process, CMS remains in contact through the account managers as well as central office with the PACE organization to better understand what the root cause of the noncompliance is. So, before you get to the higher levels of noncompliance - a warning letter with a business plan or a CAP, we're going to be in contact with your organization to hear from you and to get an understanding of what is going on.

As a general rule, compliance actions are not issued when there is a sanction or enforcement action for the same issue during the same time period. So, we may take note that it has happened, but if there's a higher level of compliance in place at that same time for that same issue, we may not issue compliance right at that time.

So, to tie all of our presentation together, I wanted you all to get an understanding of why we chose these two topics and why they're related to our compliance. Payment reconciliation, PDEs, and formulary issues are topics that are currently generating compliance or have the potential to generate compliance actions. Roughly 52 percent of all compliance issues to PACE organization from January 1st of 2016 through yesterday, July 19th, 2017, relate to these two topics alone.

In that timeframe, 48 compliance actions were issued to PACE organizations. Now, that may not sound like a lot, given the breadth of the Part D program, however PACE is a very small component, with less than 200 organizations at last count. So, 48 notices is actually sort of significant. There were 42 notices of noncompliance, five (5) warning letters, and one (1) CAP. Eight (8) of the 48 notices were formulary-related, and 17 of the 48 notices were payment related, either to DIR or PDEs. The one CAP, which is the highest notice that we will issue, was PDE related.

So, to Angela's point, to Teddy's point, the formulary issues, the payment issues, they are real issues. They are generating compliance. Like I said, our highest action that we will issue was payment related to -- it was specific to PDEs. So, if you all are having issues with these things, we have two mailboxes listed. Please submit your questions. If you don't feel comfortable asking them today, we're always available to you.

We would like to get an understanding of what you may not understand, if you're having difficulty submitting the information or you're unclear what constitutes a formulary, so that we can help you, so that -- and the PACE participants are not affected by this. And I will also offer my personal email address to you all, and it's my name, it's Jasmine Myers-Duncan -- and my name is spelled out in the beginning of the presentation -- @cms.hhs.gov. Feel free to email me with your questions. And if I cannot answer it directly, I will certainly direct you to the person who will be best able to assist you.

Kaye Rabel: All right. At this time, our session is out of time, and we don't have time for questions, but you will have an opportunity to ask this session questions during our open Q&A session at the end of the day. And I would like to thank our presenters, Angela, Jasmine, Teddy, and Christine for the information on Part D Payment Policy.

Okay. It's that time again to evaluate the session. Go ahead and take out your phones or computers and text your response, or go to the Poll EV link and enter your response "A" to the question "I would like to evaluate the session," and send your response.

Okay. Our last presenter for the day, she will discuss program agreements, including the purpose, roles, and timeliness. From the

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Division of Medicare Advantage Operations, please welcome Denise Osborn-Harrison.