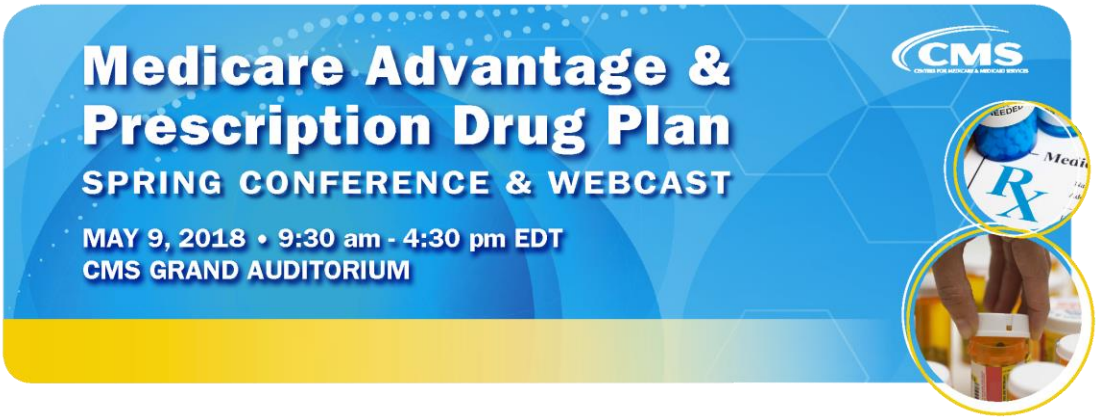

CARA/Opioids

Lisa Thorpe, CM
Michelle Ketcham, CM
Gail Sexton, CM
Sabrina Sparkman, CM

Kaye Rabel: Our next session features a panel discussion with representatives from CMS who will provide an overview of the Medicare Part D opioid overutilization policies in the 2019 Final Call Letter and C and D rules related to the implementation of the Comprehensive Addiction and Recovery Act of 2016, or the CARA drug management programs, for 2019.

I am happy to introduce to you Lisa Thorpe, Michelle Ketcham, Gail Sexton, and Sabrina Sparkman.

Lisa Thorpe: Good afternoon. We're mostly going to present sequentially today, but we will trade back and forth for a couple of slides.

First I'll present about the provisions of the Final Rule that implement Part D drug management programs for Plan Year 2019. Gail will step in to talk about the relationship of the SEP to such programs, and Sabrina will address appeals in the context of such programs.

After drug management programs, Michelle will talk about other Part D initiatives that address opioid overutilization and the impact these initiatives have had on reducing overutilization.

CARA/Opioids

Lisa Thorpe, CM
Michelle Ketcham, CM
Gail Sexton, CM
Sabrina Sparkman, CM

We published the Final Rule on April 16th in the Federal Register which contains provisions to implement the Comprehensive Addiction and Recovery Act of 2016 that we refer to as CARA. The major change that CARA and this Final Rule bring to the Part D program is that sponsors with drug management programs will be able to require an at-risk beneficiary to obtain frequently-abused drugs from a selected pharmacy and/or prescriber. Such an arrangement is commonly known as Lock-In in Medicaid and commercial plans. Until CARA was passed by Congress, there was no authority in the Part D program for Lock-In. But with this final regulation, now there is.

We've included the link to the Final Rule on this slide for your reference. Since drug management programs are new to Part D, we encourage everyone to read the relevant provisions. They not only cover the regulations that were finalized but provide extensive initial guidance as well.

Also the drug management program slides in this presentation do not touch on every aspect of such programs nor tease out all the nuances. Rather, they provide an overview and touch on some highlights.

The next two slides provide an overview of the general structure of Part D drug management programs, after which I'll go into more detail on some of the topics. This structure should be familiar to sponsors and anyone else who is familiar with our current Part D overutilization monitoring system, or OMS. This is because in implementing the drug management program provisions we integrated them with the current OMS.

So under drug management programs there are clinical guidelines that are used to identify potential at-risk beneficiaries. Please note we're going to do our best to stay away from the acronym PARB or referring to

beneficiaries as PARB, and also avoid speaking some of the other acronyms on these slides. We only use them to save space in the presentation. So if we slip, feel free to call us out, but we will also do the same.

I'd like to point out that clinical guidelines is the CARA statutory term. Frankly, it's not the best term for drug management programs as clinical guidelines are typically about treating patients. However, in the context of drug management programs, clinical guidelines refer to identifying potential at-risk beneficiaries who may be abusing or misusing certain drugs. They do not refer to dosing limits or anything like that.

Clinical guidelines are equivalent in concept to the OMS criteria that currently identify beneficiaries who may be overutilizing opioids, so I think you'll see that we will all continue to use the term "OMS criteria" in relation to drug management programs much more frequently than we'll refer to "clinical guidelines."

Drug management programs will only apply to controlled substances that are designated as frequently-abused drugs.

And finally, there are categories of beneficiaries who are exempted from drug management programs.

So I'll continue with an overview of the general structure of Part D drug management programs. As with OMS today, a sponsor must have written policies and procedures for their drug management programs. Also, once a beneficiary is identified as a potential at-risk beneficiary, the sponsor must conduct case management with the prescribers for the purpose of engaging in clinical contact and verifying if the beneficiary is an at-risk beneficiary.

Sponsors must report the results of case management to OMS quarterly until the case is resolved, as they do today.

There is no deadline for sponsors to complete case management although we do monitor for outliers. We want sponsors to be thorough and accurate while also diligently addressing opioid overutilization in their plans just as they do today under OMS.

Based on the results of case management, a sponsor may make a determination that a beneficiary is an at-risk beneficiary and place a limitation on their access to coverage for frequently-abused drugs.

Currently under OMS, sponsors can implement a beneficiary-specific point-of-sale edit to prevent coverage of opioids beyond what is medically necessary or that beneficiary. They will still be able to do so under drug management programs, but they may also decide that pharmacy or prescriber Lock-In is a better approach to a particular beneficiary as long as they follow the requirements in the Final Rule.

As to Lock-In, a beneficiary will generally be locked in to the prescriber or pharmacy that they prefer unless an exception applies. And a sponsor must ensure that the beneficiary has reasonable access to drugs that are determined to be frequently-abused drugs.

The Final Rule requires two beneficiary notices whereas under OMS today only one is expected.

And, of course, the beneficiary has appeal rights under drug management programs, which Sabrina will cover later.

And while coverage limitations can be extended, they have a termination date under the rules we finalized, which is different from OMS today.

So that was an overview of the general structure for Part D management programs in the Final Rule, and now I'll touch on some specifics.

These are the OMS criteria for 2019 that will identify potential at-risk beneficiaries who may benefit form a drug management program if the sponsor determines them to be at risk. As you can see, the OMS criteria in 2019 will continue to identify beneficiaries who are receiving opioids from multiple prescribers and pharmacies.

Also, we finalized minimum and supplemental criteria, which is a different approach from the current OMS criteria. Part D sponsors must review every beneficiary in their plans who meet the minimum criteria, and they may review beneficiaries who meet the supplemental criteria.

Beneficiaries who meet the minimum criteria will be reported to plans by OMS, but we do not plan to report beneficiaries who meet the supplemental criteria at this time.

We adopted the structure to make sure that we required plans to review a program size for which plans had provided input that such a size was manageable, as required by CARA. But given the national opioid crisis, we wanted to allow plans to review more beneficiaries if they have the capacity while we still keep parameters around which beneficiaries and how many sponsors may review since Lock-In is new to Part D.

As you just saw, the OMS criteria for 2019 will identify at-risk beneficiaries that are based on the beneficiaries' opioid use. However, we have designated opioids and benzodiazepines as frequently-abused drugs for

2019 so that sponsors are able to address concurrent use through their drug management programs. Concurrent use can be dangerous and will be reported by a flag in OMS. This means that if a beneficiary is determined to be at risk, the coverage limitation may apply to opioids and benzodiazepines. Thus, if the coverage limitation is a pharmacy Lock-In, for example, the sponsor may require the beneficiary to obtain opioids and benzodiazepines from the selected pharmacy.

I'd also like to point out that the Final Rule establishes a structure that will allow for changes in the OMS criteria and frequently-abused drugs through the call letter process for 2020 and beyond as long as the criteria and drugs meet the finalized definitions of clinical guidelines and frequently-abused drugs which are not on the slide but you can read them in the Final Rule. This will provide flexibility for CMS and stakeholders to address the opioid epidemic beyond 2019 as necessary.

The Final Rule exempts certain categories of beneficiaries from drug management programs. As with OMS today, these are beneficiaries that are being treated for active cancer-related pain or who are in hospice. The Final Rule also exempts some additional categories which are beneficiaries who are receiving palliative or end-of-life care and those who are residing in a long-term care facility or any facility for which opioids and benzodiazepines are dispensed to residents through a contract with a single pharmacy.

Sponsors must conduct case management for each at-risk – potential at-risk beneficiary to make sure the beneficiary's care is properly coordinated due to the multiple prescribers and pharmacies. The requirements for case management are similar to what sponsors do today under OMS. Although we've finalized requirements for case management, sponsors have some flexibility in how to approach it across

their drug management programs or by beneficiary as they do today under OMS.

We've heard from sponsors that under the current OMS process, the mere sending of a detailed written report on the beneficiary's total opioid utilization is sometimes sufficient to resolve the case. In such cases, the prescribers may realize the beneficiary is at risk but also know that adjusting their care for their patient is sufficient to eliminate the risk. In other cases, sponsors may decide that the case requires more immediate and direct contact with the prescribers, for example by telephone.

Once the sponsor has completed case management, the sponsor will determine if the beneficiary is an at-risk beneficiary for whom it will implement a limitation on that beneficiary's access to coverage for benzodiazepines and opioids.

There are requirements a sponsor must meet before limiting such access. They must conduct the case management. They must obtain the agreement of at least one prescriber, but there are some exceptions. They also must provide the required beneficiary notices.

So prescriber verification of whether a beneficiary is at risk and prescriber agreement are related topics. The purpose of this chart is to show the relation. CARA requires that a sponsor verify that the beneficiary is at risk unless the prescriber is not responsive, which serves as the prescriber's opinion, but it's the plan sponsor that makes the at-risk determination.

Prescriber agreement is required under the Final Rule for prescriber Lock-In. It is not required for pharmacy Lock-In. And it is required for a beneficiary-specific POS edit unless the prescriber is not responsive.

So to demonstrate that a prescriber is not responsive under the Final Rule, the sponsor must make attempts to reach the prescriber three times within ten business days.

Sabrina will step in at this point for a slide to talk about at-risk determinations.

Sabrina Sparkman: Thank you, Lisa, and good afternoon.

In the Final Rule, we included a definition of at-risk determination. An at-risk determination is a decision made under a plan sponsor's drug management program that may involve identification as an at-risk beneficiary, a limitation or a subsequent continuation of a limitation on access to coverage for frequently-abused drugs. In other words, a beneficiary-specific point-of-sale edit or the selection of a prescriber and/or pharmacy for purposes of Lock-In and information sharing for subsequent plan enrollment.

Upon identification as at risk, the enrollee will receive a second written notice explaining the limitations, for example, prescriber and/or pharmacy Lock-In, and their appeal rights. If the limitation is extended beyond the initial 12-month period, the enrollee will receive an additional written notice. Additional information regarding extensions will be discussed later.

Now I'll turn it back to Lisa to discuss these notices in further detail.

Lisa Thorpe: As to the beneficiary notices, this slide does not depict everything that's included in an initial notice. It just highlights certain aspects in the interests of time and space.

The sponsor provides the initial notice to the beneficiary after case management to inform the beneficiary that the sponsor has identified them as a potential at-risk beneficiary and intends to limit their access to frequently-abused drugs or opioids and benzodiazepines.

It also includes a description of the proposed coverage limitation whether it be pharmacy or prescriber Lock-In or a beneficiary-specific edit.

The initial notice explains to the beneficiary that they have 30 days to submit relevant information to the plan and to also submit their preferences for a pharmacy or a prescriber if that's applicable.

The initial notice informs the beneficiary that the sponsor must make a decision within 60 days. And it also includes information if there is any limitation on the availability of the Duals SEP due to the beneficiary being identified as a potential at-risk beneficiary.

Again, this slide does not depict everything that's included in the second notice. The sponsor provides the second notice to the beneficiary after reviewing any information that the beneficiary has submitted to inform the beneficiary that the sponsor has, in fact, identified them as an at-risk beneficiary and that the sponsor is limiting their access to coverage for opioids and benzodiazepines.

The second notice also includes a description of the coverage limitation with the effective and termination dates.

If the limitation is a pharmacy or prescriber Lock-In, the second notice will include the selected pharmacy or prescriber from which the beneficiary must obtain these drugs.

If the beneficiary hasn't submitted any preferences for prescribers, the second notice will inform them that they still can.

The second notice must also include information if there is any continuing limitation on the availability of the Duals SEP due to the beneficiary being identified as an at-risk beneficiary.

And finally, the second notice must contain information on the beneficiary's right to a redetermination.

So there's the possibility that a sponsor may not determine that a beneficiary is an at-risk beneficiary based on information the beneficiary submits in response to that initial notice. We do not expect this to happen frequently since sponsors should be very thorough in their case management. But when it does occur, then the sponsor must send the beneficiary an alternate second notice to let them know that no coverage limitation will be implemented.

Also, the alternate second notice would inform the beneficiary that the SEP limitation is no longer in effect if that's applicable. Thus, the second notice and the alternate second notice serve as confirmation notices for the beneficiary one way or the other as to their status. And they are new from the perspective of what occurs currently in OMS, which just has the one notice.

As far as timing of the second and alternate second notice, they must be sent no less than 30 days after the initial notice. That's in order to give the potential at-risk beneficiary sufficient time to provide any relevant information.

Also, in order for the beneficiary to have a definitive date by which they know whether the sponsor has determined them to be at risk or not, the sponsor must send the second notice or the alternate second notice, whichever applies, not more tthan the earlier of the date that the sponsor makes the determination or 60 days after the initial notice.

So on this slide we've included two examples to illustrate the timing of the notices, one for proposed pharmacy Lock-In that does occur and one for proposed prescriber Lock-In that does not occur. I'm not going to read it, but you have it for reference later, and we plan to include additional examples in guidance.

There is one exception to the requirement for the sponsor to send initial notice, and that is for an at-risk beneficiary who switches plans and the gaining plan continues the exact same coverage limitation. In such a case, the beneficiary would have received the initial notice from the immediately-prior plan which contained the information that they are entitled to. The gaining plan must send a second notice concurrent with the adoption of that limitation to alert the beneficiary that the coverage limitation will continue in the new plan. This occurs today under OMS as well.

So now I'm going to turn it over to Gail to talk about the Duals SEP limitation.

Gail Sexton: Okay. Thank you, Lisa. Good afternoon.

Amongst other things, the CARA legislation gave the Secretary the authority to limit the Duals Special Enrollment Period, or SEP. Currently the SEP for Duals and for those receiving extra help is continual. It allows for changes on a monthly basis.

However, the changes in the Final Rule will limit the scope of the Duals SEP. Duals SEP will be allowed to be used one time per calendar quarter for the first three calendar quarters of the year. There won't be a separate Duals SEP for the fourth quarter, but Duals, like all other beneficiaries, will have the annual enrollment period if they wish to change plans.

In limiting the Duals SEP, we wanted to coordinate the limitation with the implementation of the drug management programs as we believe that the intent was to limit plan changes to allow for the care coordination that a drug management program is intended to provide.

So once a beneficiary is identified as potentially at risk, they will no longer be able to use the Duals SEP to change plans. However, these beneficiaries can use the AEP, the Annual Election Period, and other SEPs for which they meet the criteria.

Once a sponsor identifies an individual as a potential at-risk beneficiary, the sponsor, with limited exceptions, is required to provide an initial notice to the beneficiary which includes notification that the Duals SEP is no longer available. The effective date of the limitation will be the date on the initial notice.

If the Part D plan sponsor takes no additional action to identify the individual as an at-risk beneficiary within 60 days from the date on that initial notice, the potential at-risk designation and the Duals SEP limitation will end. If the plan proceeds to identify the beneficiary as at risk, the Duals SEP limitation will not expire until the earlier of either the beneficiary leaving the plan, a subsequent determination including a successful appeal that the individual is no longer at risk, an initial 12-month period with the sponsor's option to extend for a maximum of 24 months in total. That's an additional 12-month period upon reassessment

of the beneficiary's at-risk status at the completion of the initial 12-month period.

And now I'll turn it back over to Lisa to talk about beneficiary preferences and reasonable access.

Lisa Thorpe: So the Final Rule provides that in the case of a beneficiary who is locked in, the sponsor must accept the beneficiary's preferences for the selected pharmacy or prescriber as long as the preference is in network unless an exception applies.

Since stand-alone PDPs do not have prescriber networks, they have to accept the preference of the at-risk beneficiary for a prescriber if the coverage limitation is a prescriber Lock-In unless an exception applies.

The exception is if the sponsor determines that the selection would contribute to drug abuse or diversion and there is strong evidence of inappropriate action by the prescriber, the pharmacy, or the beneficiary. We expect that the use of this exception will be very limited given that the selection generally has to be an in-network prescriber or pharmacy. However, in cases where the sponsor asserts that this exception applies and the sponsor changes the selection, the sponsor must provide the beneficiary of 30 days advance written notice and a rationale. Please note that the beneficiary may submit prescriber and pharmacy preferences at any time as alluded to earlier.

When a pharmacy or prescriber is selected, the plan sponsor must ensure in their drug management programs that the at-risk beneficiary has reasonable access to opioids and benzodiazepines, which may necessitate the selection of more than one prescriber or pharmacy. For example, reasonable access may mean that the beneficiary sees a

primary care physician who prescribes opioids and a psychiatrist who prescribes benzodiazepines. It also means that a sponsor may need to allow an at-risk beneficiary to see an out-of-network prescriber or pharmacy.

In making the selection, the Final Rule lists several factors as a non-exhaustive list that must be taken into account in determining reasonable access, such as geographic location, multiple residences, the beneficiary's predominant use of a prescriber or pharmacy, natural disasters, or other urgent situations.

As noted earlier, coverage limitations have a termination date. Under the Final Rule, and I think Gail just went through this, they shall terminate the earlier of the date the beneficiary determines that they are no longer likely to be at risk without the limitation or at the end of a one-year period unless the limitation is extended for an additional year, in which case the end of a two-year period.

To extend a limitation, a sponsor must determine that there is a clinical basis for such an extension. The sponsor must also obtain the agreement of a prescriber with some exceptions. Such agreement is not required for pharmacy Lock-In. Recall that the prescriber agreement is not required for pharmacy Lock-In initially either. Also, prescriber agreement is not required for a beneficiary-specific edit to be continued but only if the prescriber is not responsive. Recall that a POS edit may be implemented if prescribers were not responsive.

So these exceptions are in line with how the coverage limitations may be put in place in the first place.

If a sponsor does extend the limitation, it must provide a second notice to the beneficiary. Again, those end dates will need to be updated.

So that was an overview of the structure of drug management programs. Again, it definitely did not cover everything that's in the Final Rule, but we hope it provided a picture of how such programs will work generally.

And now I'll turn it over to Sabrina again to talk about appeals in the context of drug management programs.

Sabrina Sparkman: Thank you, Lisa.

At-risk determinations are subject to the existing Part D benefit appeals process. An enrollee has the right to request a redetermination and potentially higher levels of appeal if he or she disagrees with a determination made under a drug management program.

An enrollee has 60 days from the date of the second notice to request an appeal unless there is good cause for late filing, which would be determined on a case-by-case basis.

In the event that there are multiple disputes raised in a single appeal request, they must be adjudicated as a single case. For example, if an appeal request includes a dispute related to a point-of-sale edit and the selection of a pharmacy, the adjudication of the appeal would include both issues.

As previously mentioned, at-risk determinations will use the existing Part D benefit appeals process and are subject to the standard and expedited processes. The timeframes for a plan redetermination and IRE reconsideration are the same. The standard timeframe is no later than

seven days, and the expedited timeframe is no later than 72 hours. In each case, the enrollee must be notified of the decision as expeditiously as their health condition requires.

At-risk determinations made under a plan sponsor's drug management program may be changed. One means that may facilitate a change is the appeals process. An enrollee, an enrollee's representative, or their prescribing physician or other prescriber may dispute a determination and the change is made on the appeal.

Another means to facilitate a change is a new at-risk determination made by the plan sponsor. Through ongoing case management, the sponsor may make a new at-risk determination that changes the previously-implemented limitation. And this new at-risk determination is subject to appeal. We would expect any changes to be made infrequently.

In addition to the right to appeal an at-risk determination, an enrollee always retains the right to request a coverage determination, including an exception for any drug that he or she believes may be covered under Part D.

If the 60-day timeframe to appeal has passed and, for example, an enrollee wishes to make a change to a point-of-sale edit, he or she may ask for a coverage determination. An approved coverage determination could result in a change to a previously-imposed limitation.

As with other Part D redeterminations, in notifying an enrollee of a redetermination of an at-risk determination, the plan sponsor may use CMS's model redetermination notice or they may develop their own. Notification of an adverse decision must clearly explain the reason for the denial and include the enrollee's appeal rights to the IRE.

Notification of a favorable decision must explain the conditions of approval and specifically how the previous limitations under the drug management program are changing.

Any changes made by a redetermination or higher level of appeal must be effectuated using the existing effectuation requirements for Part D benefit requests.

Now I'll turn it over to Michelle to discuss additional changes for 2019.

Michelle Ketcham: Thank you, Sabrina.

So far the majority of this presentation has been dedicated to discussing the implementation of the CARA drug management programs which build upon the already-successful OMS and case management process. But given the magnitude of the opioid epidemic, CMS finalized guidance on a number of new policies for 2019 to further help Medicare Part D plan sponsors prevent and manage prescription opioid overuse. These were announced in the final 2019 call letter that was published in April. The strategies collectively work towards reducing prescription opioid overuse and address multiple facets of the issue.

The next slide summarizes the strategies finalized for 2019 in the call letter and how each approach is tailored to address distinct populations of Medicare Part D opioid users. I'm going to spend some time on this slide to review each of the items.

Starting in the top right corner, high-risk opioid users, as discussed, we are integrating the OMS with the CARA drug management programs for 2019. Potential at-risk beneficiaries meeting the minimum criteria will be reported by OMS on a quarterly basis. And sponsors with drug

management programs must review each case and report their findings back to CMS as they do today.

We're making additional enhancements to OMS for 2019 including revised OMS metrics and expanded information to sponsors about potential at-risk beneficiaries who also take opioids and potentiator drugs. The beneficiaries may be at even increased risk of an adverse event taking certain drugs combined with opioids.

Sponsors can consider this information when they perform case management.

Now OMS is primarily a retrospective tool. It focuses on a narrow population. As Lisa mentioned, we estimate almost 70,000 may be eligible and meet the OMS criteria for 2019. But sponsors should also implement safety edits across a larger population as a proactive step to engage both patients and prescribers about prescription opioid overdose risk at the time of dispensing.

Now moving clockwise, to address concurrent use in real time at the point of sale, we expect sponsors to implement soft safety edits to alert the pharmacist about duplicative opioid therapy and concurrent use of opioids and benzodiazepines.

Next moving through the graphic on the slide, sponsors should also implement other real-time safety alerts based on a cumulative morphine milligram equivalent, or MME, at the point of sale, to better coordinate care for chronic opioid users. We're advancing our guidance in 2019 with increased focus on care coordination among prescribers, patients, and pharmacists. Next year we expect all sponsors to implement an opioid care coordination safety edit at the pharmacy. These alerts should be

based on a cumulative MME threshold of 90 milligrams per day meaning it triggers when a beneficiary's cumulative MME per day reaches or exceeds 90 MME.

Sponsors may also include a prescriber or pharmacy count in the edit. Pharmacists may override this edit after consultation with the prescriber to confirm intent.

These edits are not intended to be a prescribing limit but instead give physicians important information about their patient's opioid use to prompt individualized clinical discussions and reassessment.

The edits also support the current pharmacist's workflow. They provide information on risk and complement the pharmacist's review of state prescription drug monitoring program system data.

Furthermore, we expect sponsors to implement reasonable logic to remove the likelihood that the opioid care coordination edits will trigger multiple times necessitating repeated or duplicate pharmacist-prescriber consultations.

Sponsors will also continue to have the option to implement hard MME edits and set the threshold at 200 milligrams or more, and may include prescriber-pharmacy counts.

Lastly, moving to the top left of the slide, as a new line of defense for opioid naïve patients, to reduce the potential for chronic opioid use or misuse, we expect all Part D sponsors to implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a seven-day supply.

When implementing these edits, we recommend that sponsors apply several exclusions and to avoid impacting beneficiaries' access to medication-assisted treatment.

Also, when a point-of-sale edit is triggered and cannot be resolved at the pharmacy, the sponsor is required to notify their pharmacy network to distribute a written copy of the standardized CMS pharmacy notice to the enrollee. This notice instructs the enrollee on how to contact their plan and explains their right to obtain a coverage determination from the plan including information about the exceptions process.

One question that we're very frequently asked by sponsors is if all coverage determination requests seeking an exception to an MME must be expedited. We have said that we generally expect these requests to meet the criteria for expedited review, but we don't have a blanket requirement that all of the requests must be expedited. As a reminder, if the prescriber indicates, or if the plan determines, that applying the standard adjudication timeframe could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function, the case must be processed under the expedited timeframe. So, as with any other request for benefits, the Part D sponsor should determine the need for the expedited timeframe based on the facts and circumstances of that particular case. And more information is in Sections 40 and 50 of Chapter 18 of the Prescription Drug Benefit Manual.

We plan to conduct an informal pilot to develop best practices and technical guidance for the opioid naïve seven-day supply and care coordination safety edits. This is similar to the small pilot that we did in 2012 to develop the initial opioid overutilization policy in OMS for 2013. And also a few years ago to test the MME edits.

We'd like to recruit a few volunteers to test and provide feedback on coding, provider education, and pharmacy preparedness. This is very critical for implementation. It's important that sponsors' network pharmacies and customer service representatives are adequately trained with regard to any of the edits including how pharmacists can review or override the care coordination safety edits. When appropriate, such edits should be resolved at point of sale. We definitely don't want patients turned away unnecessarily.

Or as already discussed, when edits are not resolvable, patients should provide the standardized CMS pharmacy notice explaining the enrollee's right to obtain a coverage determination from the plan.

Any plan sponsors who are interested in participating in the pilot should email PartD_OM@CMS.HHS.gov.

The timeline is on the next slide. We plan to recruit volunteers this month for the pilot and determine which edit they would like to test and how it will be tested.

We plan to conduct the pilot this summer and hold regular calls with participants.

Then this fall we plan to release additional technical guidance as needed on the new opioid strategies for 2019, CARA drug management programs, and other system changes related to OMS and MARx.

We also use quality measures to drive performance improvement in the Part D program. We currently report several Pharmacy Quality Alliance, or PQA measures, to Part D sponsors through monthly reports via the Patient Safety Analysis website. These reports include summary rates,

information about specific beneficiaries identified, and plan sponsors with the lowest rating on each measure report actions to CMS they will take to improve performance.

Many of the measures are also displayed on CMS.gov as display measures or Medicare.gov Plan Finder as Part D Star Ratings.

We have been reporting three PQA opioid overuse measures since 2016 to track trends in opioid overuse across Part D. Sponsors may use the report to supplement their drug utilization review programs. We will continue to report these measures, and will add one of the measures, the use of opioids at high dosage and from multiple prescribers, to the 2019 display page.

We'll also begin to report the concurrent PQA – the PQA measure concurrent use of opioids and benzodiazepines. Actually we already started reporting this as of April for the 2018 measurement year. We plan to add the measure to the display page for two years, and we'll consider this measure for the 2023 Star Ratings pending rulemaking.

I do not have any trends yet to – year-over-year trends yet – to report on these new quality measures. However, in the next two slides I will present some data analysis of opioid utilization in Part D demonstrating the impact of the Part D policies.

This slide shows the percent of Part D enrollees who used opioids between 2013 and 2017. Despite increasing Medicare Part D enrollment, the percent of opioid users has steadily decreased from 31.2% in 2013 to 27.9% in 2017.

In developing the OMS for 2013, as I mentioned we conducted pilots and testing in 2012. So we used 2011 as the pre-pilot, pre-policy measurement period. Since that time, the number of beneficiaries meeting the OMS criteria that was in place between 2013 and 2017 decreased by 76%. The greatest decrease, 40%, was observed from 2016 to 2017.

We updated the OMS criteria in 2018 to incorporate best practices and align with the CDC guideline. And as we already discussed, the OMS criteria will be expanded again in 2019 with the implementation of CARA drug management programs.

We also examined the number of beneficiaries reported through OMS to Part D sponsors who are new outliers compared to repeat outliers. Going back to the 2013 reports, the number of first-time potential high-risk overutilizers decreased by 81%. The number of repeat outliers decreased by 65%. So the enhanced retrospective review and case management process appears to be making a significant impact.

Since 2013, we've also encouraged Part D sponsors to use formulary-level controls at point-of-sale including safety edits. Some sponsors began to implement cumulative MME safety edits as early as 2015. And since 2017, all sponsors are expected to implement soft or hard MME safety edits at point-of-sale.

Sponsors may currently set any soft opioid MME edit threshold at or above 90 milligrams per day. And any hard MME edits at or above 200 milligrams per day.

Here we analyzed the number of Part D enrollees that met or exceeded 90 MME for at least one day with some exclusions.

Overall, between 2012 and 2017, there was a 33% decrease in the rate of Part D enrollees meeting or exceeding 90 MME for at least one day with the largest decrease in 2017 which coincided with CMS releasing more specific guidance for all Part D sponsors to implement MME edits and uptake of the CDC guideline which was published the prior year.

We also observed a larger 49% decrease in the number of Part D enrollees meeting or exceeding 200 MME for at least one day between 2012 and 2017.

So in closing, we will continue monitor progress in reducing prescription opioid overuse through data analysis and quality metrics. We are particularly concerned with protracted, high-risk use without routine reassessment and care coordination to manage the patient's risk. In some cases, it may be appropriate to taper opioids to a lower dosage or to taper and discontinue opioids, but this is an individualized decision and may require time, can be very challenging, and should not be done abruptly or without consent and buy in with the patient.

We expect that communication and interactions between the pharmacists, prescribers, and patients will be an integral component of sponsors' drug utilization management programs, especially as sponsors implement the new strategies for 2019. We will continue to work with all stakeholders to help address this devastating impact. And the commitment shown by the Part D plans and our federal partners has been tremendous.

The remaining slides provide additional information on resources. Here are the webpages on CMS.gov to find the Medicare Part D opioid overutilization guidance and the Part D appeals guidance. And as I

mentioned, we will be updating this information over the next several months.
Also, eligibility and enrollment guidance are provided in Chapter two and three of the Prescription Drug Benefit Manuals.

And finally, email boxes at CMS by topic are listed here to make sure your questions are triaged to the right team.

Thank you so much for your attention, and this now concludes our session.

Stacey Plizga: All right. Well I would like to thank our panel of speakers for providing the overview of the Medicare Part D opioid overutilization policies. We don't have any time right now for questions, however, if you would like to evaluate this session, please go ahead and take out your cell phone and answer A to the question, I would like to evaluate this session. Or if you are in our viewing audience, you could use your iPad, tablet, or computer. And then go ahead and click on the link, follow it, and follow the instructions.

All right. We have a slight change to our agenda today. And instead of the Administrator speaking right now, we are going to take a 15-minute break right now, and then we will come back and then we will have the Administrator at that particular point in time. So if you could return at 2:15 promptly, we would appreciate it. Everyone enjoy your break.