# New Part D Opioid Overutilization Policies Call

**Moderated by: Nicole Cooney**
**February 14, 2019 — 1:30pm**

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Operator: At this time, I would like to welcome everyone to today's Medicare Learning Network® event. All lines will remain in a listen-only mode until the question and answer session.

This call is being recorded and transcribed. If anyone has any objections, you may disconnect at this time.

I will now turn the call over to Nicole Cooney. Thank you, you may begin.

## Announcements & Introduction

Nicole Cooney: Hi everyone. I'm Nicole Cooney from the Provider Communications Group here at CMS and I'll be your moderator today. I'd like to welcome you to this Medicare Learning Network call on the New Part D Opioid Over Utilization Policies.

During this session, our experts will discuss the New Opioid Policies for Medicare Drug Plans that CMS implemented on January 1. These new policies include improved safety alerts when patients fill opioid prescriptions at the pharmacy and Drug Management Programs for patients at risk for misuse or abuse of opioids or other drugs.

Before we get started, you received a link to today's presentation in your confirmation email. The presentation is available at the following URL, go.cms.gov/npc. Again, that URL is go.cms.gov/npc.

Today's event is not intended for the press and the remarks are not considered on the record. If you are a member of the press, you may listen in, but please refrain from asking questions during the question-and-answer session. If you have enquiries, please contact press@cms.hhs.gov.

And this time, it's my pleasure to introduce today's presenters. First, we'll hear from Beckie Peyton from our Medicare Drug Benefit Group and then Ann Kane RN, a Health Plans Manager from our Denver Regional Office. Beckie?

## Presentation

Beckie Peyton: Thank you Nicole, good afternoon everyone. My name is Beckie Peyton and I work in the Division of Clinical and Operational Performance in the Medicare Drug Benefit and Part C and D data group in the Center for Medicare here at CMS.

Together with my colleague Ann Kane in our Denver Regional Office. I'm going to talk to you today about new Medicare Part D opioid policies for 2019.

This includes an overview of the policies and important information for Medicare suppliers who prescribe opioids for their patients. The goal of today's training is to equip you with the information and resources you'll need to respond to inquiries from your patients, their prescription drug plans and dispensing pharmacies related to these policies.

Before I begin, I want to note that this presentation is a repeat of a presentation CMS delivered on December 27th, 2018. We want to be mindful of your time so if you attended the December 27th presentation, we understand if you decide to drop off this call.

We're using this slide deck titled new Medicare Part D prescription opioid policies for 2019 information for prescribers. If you'd like to follow along, you can find the slides in the attachments that were sent for today's call by clicking the presentation link and opening the webinar file and the zip file.

We will refer to slide numbers to make it easier to follow along.

A couple other notes for today, we will use the terms prescriber, provider, and doctor. We're essentially using those terms interchangeably and when using them, we're referring to health care providers who prescribe opioids.

Generally, that means physicians, but it can include others who are authorized under state and federal law to prescribe opioids such as nurse practitioners, physician assistants, and dentists.

We will also use the terms plan, Part D plan, drug plan, etcetera to refer to the Medicare prescription drug plan. This includes standalone Part D plans in which many fee for service Medicare beneficiaries are enrolled and MAPDs which are plan through the Medicare advantage programs that offer A, B, and D benefits through a single plan.

Getting started, we will turn to slide to 2. CMS understands the magnitude of our nation's opioid epidemic and its impact on communities. Opioid medications are effective at treating certain types of pain, but have serious risks such as increasing tolerance, development of opioid use disorder, and overdose.

Given the scope of the crisis, CMS published a roadmap in June 2018 outlining its efforts to address this issue. The roadmap details a three-pronged approach to combating the opioid epidemic. One, the prevention of new cases of opioid use disorder. Two, the treatment of patients who have already become dependent on or addicted to opioids, and three utilization of data from across the country to better target prevention and treatment activities.

Slide 3, CMS finalized new opioid policies for Medicare drug plans that became effective on January 1st, 2019. The new policies encourage collaboration and partnership among Part D plans, pharmacy, prescribers, and patients.

They are driven by goals of patient safety and improved care coordination to improve opioid utilization management, prevent opioid misuse, reduce serious adverse risk, and promote safer prescribing practices.

We recognize the doctors are in the best position to identify and manage potential opioid over utilization in the Medicare Part D population and that Part D plans can assist in that task by alerting you about unusual utilization patterns and prescription claims.

Slide 4, the new policies include improved safety alerts when opioid prescriptions are dispensed at the pharmacy and Drug Management Programs for patients determined to be at risk for misuse or abuse of opioid or other frequently abused drugs.

The policies which we'll describe in greater detail today are tailored to address distinct populations of Medicare Part D prescription opioid users including new opioid users referred to as opioid naïve, chronic opioid users, users with potentially problematic concurrent medication use, and high-risk opioid users.

Turning to slide 5, CMS recognizes that a one size fits all approach does not take into account different circumstances related opioid use.

For these reasons, residents of long-term care facilities those in hospice care, patients receiving palliative or end of life care, and patient being treated for active cancer related pain are exempt from the interventions that will be speaking about today.

Prescribers may provide information to the plan if their patient meets one of these exclusion categories. Also access to medication-assisted treatment MAT such as buprenorphine will not be impacted by these initiatives. CMS recognizes the importance for patients who are on MAT drugs to continue therapy without disruption.

Turning to slide 6, I will review some myths about the new policies.

Here at CMS, we've heard a lot of misconceptions out there about our policies including assumptions that Medicare is imposing restrictive policies that have been seen in some commercial and state Medicaid plans.

For example, we've heard that some prescribers and patients think that Medicare is requiring that all opioid prescriptions be limited to fills of 7-days at a time. This is false. The 7-day supply limit policy, which I'll describe in greater detail only applies to Medicare Part D patients who have not filled an opioid prescription recently. For example, within the last 60 to 90 days.

This limit does not apply to patients already taking opioids including chronic opioid users.

Slide 7, There are also fears that Medicare is imposing prescribing limits or forcing all patients to taper prescription opioids below a certain amount. This is also false. CMS believes that decisions to taper or stop prescription opioids must be carefully considered and are individualized decisions between the patient and their prescriber.

We recognize that there may be serious risks when patients abruptly discontinue opioid or rapidly taper high dose opioid use. This can be especially challenging for patients taking high doses or those taking opioids for extended periods of time.

CMS is implementing policies that aim to strike a better balance in addressing opioid overuse that avoids negative impact on the patient doctor relationship, preserves access to medically necessary drug regimens, and reduces the potential for unintended consequences. These policies promote routine monitoring by physicians to periodically review opioid regimens for safety and efficacy. They're not prescribing limits.

Slide 8, we've also heard from prescribers who feel there's nothing they can do to help their patients who may be impacted by these policies. This is false. In fact, doctors play a very important role in helping patients in these circumstances.

As with other Part D coverage limitations such as prior authorization if the patient is subject to an opioid safety edit at the pharmacy, and the issue cannot be resolved at the point of sale, the prescriber can contact the plan to ask for a coverage determination on their patient's behalf.

Prescribers can also request a coverage determination at the point of care before the patient goes to the pharmacy. To obtain approval from the plan, the prescriber need only attest to the plan that the cumulative MME level or the day supply is the intended and medically necessary amount. This information can be given to the plan verbally or in writing.

## Opioid Safety Alerts

Turning to slide 9, so now I'll spend some time talking a little more in depth about the new point of sale safety alerts. Medicare drug plan's commonly implement safety alerts for pharmacists to review at the time of dispensing to prevent unsafe use of drugs. These alerts will flag the pharmacist to review for potential drug-drug interactions, therapeutic duplication or potentially incorrect drug dosage.

Part D plans are also expected to implement real time opioid safety alerts, which are also known as pharmacy claim edits as a preventive step. So, when a patient presents an opioid prescription at the pharmacy, the pharmacist will be prompted to conduct additional safety reviews at the time of dispensing.

The new opioid safety alerts include soft edits which are edits that a pharmacist can override on his or her own and hard edits which are edits that the pharmacist cannot override without the plan needing to authorize coverage. Generally, this is done after a successful coverage determination or appeal.

**POST CALL CLARIFICATION: The above sentence should read:**
**Generally, this plan authorization is done after a successful coverage determination or appeal.**

CMS expects sponsors to implement the following formulary level opioids safety edits at point of sale. The 7-day supply limit for initial opioid fills for opioid naive patients, this is a hard edit. The Care Coordination edit at 90 MME, which is a soft edit. The concurrent opioid and benzodiazepine use edit, which again is a soft edit. Duplicative long acting opioid therapy, which is a soft edit and then optional safety alert at 200 MME or more which is a hard edit.

We'll describe in detail more each of these alerts in the following slide.

So, turning to slide 10, for the 7-day supply limit for opioid-naive, this is a hard edit as I mentioned to limit initial dispensing of opioids to supply 7-days or less.

Hard safety edit stops the processing of a prescription at the pharmacy until an override is entered or authorized by the plan. This policy will affect Medicare patients who are opioid-naive which means they have not filled an opioid prescription recently, for example within the past 60 days when they present a prescription at the pharmacy for an opioid pain medication for greater than a 7-day supply.

As we mentioned earlier, this alert should not impact patients who already take opioids. A pharmacist can dispense partial quantities of an opioid prescription consistent with state and federal regulation. This means for example if the prescription is written by the prescriber for 10-days, the pharmacist could ask the patient if they would like to have a partial fill of the prescription and fill the prescription for a 7-day supply rather than the 10 days. CMS's goal with this policy is to reduce the potential for chronic opioid misuse through closer management of opioid naïve patients.

Turning to slide 11, I would like to reiterate when the opioid naive 7-day supply limit is triggered, the opioid-naïve patient may receive up to a 7-day supply at the pharmacy.

We implemented this to make sure that people, to limit the amount of time, people would leave without receiving anything. What happens after the patient receives the initial 7-day supply or if the patient needs more than a 7-day supply is where the prescriber comes in.

If the prescriber assesses upon re-evaluation that the patient will need additional therapy, subsequent prescriptions filled within the look back period again for example 60 to 90 days will not be subjected to the 7-day supply limit as the patient will no longer be considered opioid naive.

Slide 12, if a prescriber believes that an opioid naive patient will need more than a 7-day supply initially, the provider can proactively contact the plan to request the coverage determination on behalf of the patient attesting to the medical need for a longer supply.

The attestation can be given verbally. The patient and the prescriber also has the right to request an expedited coverage determination including in advance of prescribing for example prior to a patient having a surgical procedure if a longer duration is needed. Again, the prescriber need only to attest to the plan that the day supply is intended and it's medically necessary for that patient.

Turning to slide 13, another safety alert implemented in 2019 is the Care Coordination alert. This is a proactive step to give prescribers more information in some cases to encourage prescribers to discuss the opioid overdose risk and prevention with their patients, especially if the patient is receiving prescription opioids for multiple prescribers or pharmacies.

This safety alerts include the 90 MME threshold for identifying potentially high-risk patients who may benefit from closer monitoring and Care Coordination. It doesn't mean that prescriptions written for only 90 MME or less will be covered.

The alert will affect Medicare patients when they present an opioid prescription at the pharmacy and their cumulative MME per day across all of their opioid prescription reaches or exceeds 90 MME. It's important for prescribers to understand that the plan has the flexibility to modify the Care Coordination safety edit parameters.

Some plans use this alert only when the patient uses multiple opioid prescribers and/or opioid dispensing pharmacies. Prescribers may be contacted by the pharmacy for only some of their Medicare patients that meet or exceed 90 MME, but not for all depending on which Part D plan the patient is enrolled in.

In reviewing this alert, the pharmacist may need to consult with the prescriber to confirm medical necessity for the higher MME. Upon consultation, the pharmacist can then indicate that the attestation was obtained from the prescriber and the claim can be paid. Again, this is a soft edit and can be resolved at the pharmacy subsequent to this consultation between the pharmacist and the prescriber.

Turning to slide 14, again we want to emphasize that the Care Coordination edit is not a prescribing limit. As mentioned earlier, the goal of the policy is to balance addressing opioid over use without negatively impacting patients and by preserving access to medically necessary drug regimens.

The alert will be triggered by the fill of the prescription that reaches the cumulative 90 MME threshold or greater. This may involve one prescription, or it may involve multiple prescriptions in multiple drugs.

The prescriber who writes the prescription that triggers the alert is the one who would be contacted by the pharmacy even if that prescription itself is below the 90 MME threshold.

CMS encourages prescribers to respond to pharmacist outreach in timely manner to confer medical need and to give the appropriate training to on-call prescribers when necessary to resolve opioid safety edits expeditiously and to avoid disruption of therapy.

Slide 15, in response to the Care Coordination edit, once the pharmacist consults with the prescriber on a patient's prescription, the pharmacist does not have to consult with the prescriber on every opioid prescription written for the same patient after that and left the plan implements further restrictions.

If the prescription cannot be filled at the pharmacy for example if the prescriber cannot be reached for the consultation or the prescriber was consulted, but does not verify the medical necessity of the prescription or the pharmacist does not fill the prescription based on clinical judgment, the prescriber or the patient has the right to request the coverage determination on the patient's behalf for the drug including the right to request an expedited or standard coverage determination in advance of prescribing.

I'm now going to turn it over to my colleague Ann Kane to talk about additional safety edits. Thank you.

Ann Kane: Thanks Beckie and so now we are halfway through the presentation and on slide number 16. Other soft edits will trigger when the patient is taking opioids and benzodiazepines concurrently or is taking multiple duplicate long acting opioids. In designing the concurrent opioid benzodiazepines safety alert, the plan may factor in whether the patient is using different prescribers as well as the dose or day supply of prescribed medication.

In designing the duplicate long acting opioid edits, the plan may define duplicative therapy at the drug or class level and will when possible consider situations when patients switch between doses. The pharmacist will conduct additional safety reviews to determine if the patient's opioid use is safe and clinically appropriate before overriding the alert, the prescriber may be contacted.

Slide number 17, some plans may implement a hard safety alert when a patient's cumulative opioid daily dosage reaches 200 MME or more. Some plans use this alert only when the patient uses multiple opioid prescribers and/or opioid dispensing pharmacies. Again, this is not a prescribing limit. Decisions to taper or discontinue

prescription opioids are between the patient and the prescriber. However, this alert stops the pharmacy from processing the prescription until an override is entered or authorized by the plan through the coverage determination process.

Slide number 18, on the patient's behalf, the physician or other prescriber has the right to request a coverage determination for the drug or drugs, including the right to request an expedited or standard coverage determination in advance of prescribing an opioid. In the absence of other submitted and approved utilization management requirements, the plan should allow the patient to access his or her medications once the prescriber or prescribers attest that the identified cumulative MME level is the intended and medically necessary amount for the patient. This may be done verbally.

Slide number 19, if one of these opioid safety alerts is triggered and the prescription cannot be filled as written or cannot be resolved at the pharmacy, the pharmacist should provide a written copy of the standardized CMS pharmacy notice to the patient.

The patient, the patient's representative, or the physician or other prescriber on the patient's behalf has the right to request a coverage determination for a drug or drugs subject to the alert, including the right to request an expedited or standard coverage determination and the advance of prescribing an opioid, for example, for a surgical procedure.

The time for an expedited coverage determination request applies when the prescriber indicates or the plan to decides that applying the standard time frame may seriously jeopardize the enrollees life, health, or ability to regain maximum function.

CMS generally expects coverage determinations related to any opioid safety alerts to meet the criteria for expedited review. If the request meets the criteria for an expedited review by the plan, the plan must make its decision and notify the patient as expeditiously as their health condition requires, but no later than 24-hours after receipt of the request.

The additional resources slide contains information on the notice that patient received from pharmacies about their appeal rights when a prescription is not filled as written and that is at the end of the presentation.

## Drug Management Programs

Okay. Slide number 20, drug management programs. Up to this point, we spent awhile talking about what may be expected when an opioid prescription is presented to be filled at the pharmacy.

Now I'll be switching gears and discuss the different programs that will be new in 2019 that emphasizes case work where the Medicare Part D plan will work with the pharmacy, patient, and the prescriber. The Comprehensive Addiction and Recovery Act of 2016 included provisions to give Part D plans important new tools to use in 2019 to address opioid over utilization.

To implement this law, CMS adopted a regulation so that Part D plan may implement a drug management program that limits access to certain controlled substances that have been determined to be frequently abused drugs for patients who were considered to be at risk for prescription drug abuse.

For 2019, CMS has identified opioids and benzodiazepines as frequently abused drugs. Potential at risk patients are identified by their opioid use which involves multiple doctors and pharmacies. Therefore, one of the key components of a drug management program is prescriber involvement in case management. The goal of Drug Management Programs is better care coordination for safer use.

Slide number 21, if a provider prescribes opioids or benzodiazepines for a patient who has identified as a potential at risk patient, the Part D plan will contact the provider to review the patient's total utilization patterns of frequently abused drugs. The plan will ask the prescriber are the prescription opioid medications appropriate, medically necessary, and safe for the patient's medical condition and treatment.

Is the patient at risk for misusing or abusing opioids and benzodiazepines and would one of the drug management program tools help the prescriber better manage their patient's prescription drug use.

At this point, prescribers may also help plans determine whether a patient fails - falls into one of these exemptions since the plan may not always have this information. As discussed previously, exempt categories include patients receiving treatment for active cancer-related pain in hospice care or end of life care, and palliative care or living in a long-term care facility.

Slide number 22, coverage limitations under a drug management program can include requiring the patient to obtain these medications from a specified prescriber and/or pharmacy or implementing an individualized point of sale edit that limits the amount of these medications that will be covered for the patient.

The coverage limitation tools may be put in place for 12-months and extended for an additional 12 months for a total of 24 months. Each of these tools will be described in greater detail.

Slide number 23, one potential Drug Management Programs tool is a patient specific point of sale claim edit. This is an individualized POS edit for the specific patient. It limits the amount of frequently abused drugs that may be dispensed to the patient. The limitation could be a restriction on all frequently abused drugs or limitations to specific drugs and/or specific amount, which the plan will determine on a case by case basis as a result of their review.

The plan will make every effort to obtain the prescriber's agreement for this limitation but is authorized to implement if no prescriber responds to the plans attempts of contacting the prescriber through case management.

Slide number 24, pharmacy limitation. Pharmacy limitation requires a patient to obtain prescriptions for frequently abused drugs at a certain or certain pharmacies. Before implementing this limitation, the plan must verify with the prescriber that the patient is at risk but is not required to obtain the prescribers agreement to the limitation. Patients can choose which pharmacy they prefer to use and may update those preferences as needed.

Side number 25, prescriber limitation requires the patient to obtain their prescriptions for frequently abused drugs from certain prescribers. The plan must obtain the prescribers agreement to be a prescriber and confirm the prescriber selection for this limitation. Patients can choose which prescribers they prefer to use and may update those preferences as needed.

Slide number 26, after the plan conducts case management with prescribers and before implementing a coverage limitation tool, the plan will notify the patient in writing. Plans are required to make reasonable efforts to send the prescriber a copy of the letter. The prescriber and patient will have the opportunity to provide a response to this written notice on the requested information to the Part D plan within 30 days.

If the letter identifies the pharmacy or pharmacies or prescriber or prescribers from which the patient must obtain opioids and/or benzodiazepines, the patient is given the opportunity to select a different pharmacy or pharmacies and a different prescriber or prescribers than the one identified by the plan in the letter. If the patient chooses a different prescriber, the plan must obtain that prescriber's agreement before confirming the patient's selection.

Slide number 27, after the 30-day time period if the Part D plan determines based on its review that the patient is at risk and implements a limitation, it must send the patient a second written notice confirming the specific limitation and its duration. The initial limitation period could be for a maximum of 12-months and extend to an additional 12-months.

Alternatively, if the plan determines that the patient is not at risk, it must send a written notice confirming that coverage limitations will not be implemented after all.

Slide number 28, the physician or other prescriber may request an appeal within 60 calendar days from the date of the second written notice.

Notifying the patient that he or she has been identified as an at-risk patient using the plans' usual appeals process.

If the patient or the physician or other prescriber disagrees with the at-risk determination, the patient, the patient's representative, or the physician or other prescriber may request an appeal and the changed limitations can be made as a result of an appeal. The plan must respond to the appeal request within 7-days for standard request and within 72 hours for expedited request. An expedited review must be provided when the plan determines or the prescriber states that the standard time frame may seriously jeopardize the patient's life, health, or ability to regain maximum function.

In addition to the right to appeal an at-risk determination, the patient has the right to request the coverage determination as explained previously.

Note, a prescriber who agrees with a Medicare drug plan's patient specific point of sale claim edit for a patient who subsequently decides that it is medically necessary to increase the dosage may contact the plan to do so.

Medicare drug plans are encouraged to provide a proactive avenue for prescribers to be able to contact appropriate clinical staff at the plan to revise the previously agreed upon dose limit.

Slide number 29, in summary many patients have difficulty understanding the risk of using opioids and may underestimate their chances of overdosing. Providers may want to discuss the risks of an accidental overdose or having an adverse reaction to opioid since these risks are not necessarily associated with misuse.

As the new opioid safety alerts are implemented in 2019 on going communication among the pharmacists, the Part D plan, and the prescriber will be critical. Physicians and other prescribers can protect their patients' access to medically necessary drugs by responding to pharmacists or plan sponsors' telephone calls or case management notice.

Providers will also want to initiate coverage determinations or exceptions when clinically appropriate. To avoid a prescription being rejected at the pharmacy, prescribers may proactively request the coverage determination in advance of prescribing an opioid prescription if the prescriber has assessed that the patient will need the full quantity written. For example, a plan may not be aware a patient is exempt based on a new exclusion such as cancer.

Additionally, to resolve opioid safety alerts expeditiously and avoid withdrawal or disruption of therapy, CMS encourages prescribers to respond to pharmacist's outreach in a timely manner and give the appropriate training to on-call prescribers when necessary.

So, here's some additional resources slide 30 that about the Medicare Part D opioid policies and then on slide 31 we have our epidemic resources. So that concludes my portion of the presentation and I will turn it back to our moderator and to our central office colleagues. Thank you.

## Question & Answer Session

Nicole Cooney: Thank you Ann. Before we get started on the Q&A, I'd like to set a few ground rules for today's session. First in an effort to get to as many participants as possible today, I'd ask each participant to limit themselves to one question, you can then get back in the queue, we'll keep taking questions you know up until 3 o'clock as long as we have folks in the queue.

So, you know just try to prioritize and put your most important question first. We're also going to be mindful of the time that we spend on each question and look at you know about maybe 3 minutes or so for the back and forth exchange.

So, I just hope everyone will understand we're doing that, so that we can address your questions, but also get to as many questions as we possibly can. Today's session is being recorded and transcribed as a reminder. All right Nicole, we're ready for our first caller.

Operator: To ask a question, press star followed by the number one on your touch tone phone. To remove yourself from the queue, press the pound key. Remember to pick up your handset before asking your question to assure clarity.

Once your line is open, state your name and organization. Please note your line will remain open during the time you're asking your question. So, anything you say, or any background noise will be heard in the conference.

If you have more than one question, press star one to get back into the queue and we will address additional questions as time permits. Please hold while we compile the Q&A roster. Please hold while we compile the Q&A roster.
Your first question comes from a line of Lana Crocks-Ferd.

Nicole Cooney: Hello did you have a question.

Operator: Lana, you may be on mute.

The next question comes from a line of Beth Spotz.

Beth Spotz: Hi, yes, I am from Walgreens. So, I'm from a pharmacist perspective here. Is there any legal ramification of a member with a Part D plan opting to pay out of pocket for some of the soft reject, should we not be able to get a hold of the prescriber in a timely fashion?

Nicole Cooney: Give us one second.

Beckie Peyton: Thank you for the question. Medicare doesn't have a rule about whether a beneficiary can pay out of pocket if they choose to. So that would be more you know at the discretion of the dispensing pharmacy whether they would want to accept the cash payment.

Bets Spat: Okay, thank you.

Operator: Your next question comes from a line of Leann Lewis.

Leann Lewis: Good afternoon. I have a question concerning, I am with a pharmacy software vendor and it's related to the notice of appeal that is to be provided. In reading through a lot of the documentation, there appears to be some inconsistent guidance as to when the pharmacy does have to provide that appeal and when they do not.

So, for example would they need to provide it when a Medicare Part D patient when that patient leaves the pharmacy without the prescription being paid by Medicare Part D. Would they only need to provide it when the Part D sponsor in a reject or an edit sends back that they do need to provide it?

Is there a difference between the coverage determination and the Drug Management Programs and when the notice needs to be applied? You know even in the documentation for these calls in the prescriber information in the Drug Management Programs says if the plan decides to limit coverage under a DMP, the patient and the prescriber have the right to appeal plan decisions.

The patient and prescribers should contact the plan for additional information, yet in the pharmacy tip sheet, it says under the same drug management program if the plan besides to limit coverage under the DMP, the patient and the prescriber have the right to appeal the plan's decision. Pharmacies are not expected to distribute the standardized CMS notice Medicare prescription drug coverage and your right to appeal.

So, it seems to be a little muddy and these are clear guidance on when the pharmacy has to provide it and when they do not, sorry that was so long.

Nicole Cooney: Give us one second.

Beckie Peyton: Hi, thank you for the questions. I will try to address as many of them as I can. The pharmacy notice guidance generally isn't changing. We're just folding the new policies into the existing guidance for the pharmacy notice. So, the requirement there is with some limited exceptions which again those exceptions are changing, the pharmacy notice – the pharmacy will receive the code to deliver the message anytime that the prescription can't adjudicate at the point of sale and while the code to deliver the notice is delivered usually in real time with the reject. The longstanding guidance that the notice does not have to be delivered if the issue is resolved at the point of sale is still true for the opioid safety edits.

So, if the person gets, for example, the 7-day edit, and the issue is resolved at the point of sale meaning the pharmacist can provide information that the patient is not opioid naïve, even though the 569 code was delivered, the pharmacist would not need to provide the pharmacy notice.

For drug management programs, the pharmacy notice is not required if someone is in a drug management program and hits an edit, for example if they are limited to a certain pharmacy and they try to fill an opioid prescription at a different pharmacy.

The reason for that again is because the pharmacy notice instructs the beneficiary that they have the right to a coverage determination and how to request that from their plan. Once they're in a DMP, and a limitation has been imposed, they are beyond the coverage determination process so the next logical step for them would be an appeal and those people have gotten notices from the plan explaining their next step that they disagree.

So, there is a difference between the safety edits and DMP's, but we think it's consistent with existing guidance for the pharmacy notice, and there is information about that in the FAQ documents and the other resources that are available on our website. Thank you.

Nicole Cooney: Thank you. I need to move on to the next question in the interest of time.

Operator: The next question comes from a line of Linda Siy.

Linda Siy: Hello. My question is kind of similar to the first one in that if I have a Medicare patient who does not have Part D and so therefore, they are not filing on that Part D, will they be subject to the same rules when they go to pick up their prescription, just because they are a Medicare patient.

Beckie Peyton: Thank you for the question. No these are -- these policies are for Part D only.

Linda Siy: Okay, thank you.

Operator: Our next question comes from a line of Tim Kempen.

Tim Kempen: Hi, you mentioned earlier in the presentation that residents of long-term care facilities are exempt from these opioid policies. My question is; are PACE programs and the enrollees in those programs also exempt?

Lisa Thorpe: So, for drug management programs, this is Lisa Thorpe talking, PACE plan, they're voluntary so sponsors did not have to implement them for 2019, although most did, but if a PACE plan were to implement, a Drug Management Program then they have to comply with the requirements that were finalized in the rule.

Tim Kempen:  Okay, thank you.

Nicole Cooney: Thank you.

Operator: Your next question comes from the line of Janeen Glee-Bah.

Janeen Glee-Bah: Hi, thank you for taking my call. I was wondering if CMS has any plans for excluding patients that don't use opioids for pain, I'm an advocacy manager for an organization for people that have ostomy and we have a lot of patients that have high output ileostomy and use a form of morphine to slow down the output. And so, I'm wondering you know how all of these drug management plans are related to people that take them for pain and our patients are really running into a lot of problems now trying to get the medication that they normally had no problems getting for their issues.

And also, I was wondering does— what's takes—for the states that are now mandating laws for pain management and anyone that takes opioid, what does the patient follow the Medicare protocol or the state laws? How does that work?

Sorry I think I had two questions.

Nicole Cooney: Give us one second.

Beckie Peyton: Thank you for the question. So, with respect to people who use opioids for indications other than pain, these policies are about the drugs that are being dispensed and prescribed. So, in many cases in Part D you know the medical information is separate from, for example what may be submitted on a claim and so they would not be exempt based on a diagnosis other than something that we've identified as an exemption for example a cancer diagnosis.

However those people would be able to avail themselves of the same resources that we mentioned the coverage determination process, the appeals process, and again that's really where the prescriber can help by asking for those edits for example to be lifted for their patient if they don't think that it would be appropriate and then again in Drug Management Programs there is a - before a beneficiary's limited, the plan has to conduct case management so those are conversations that the plan has with the prescribers of opioids and again that information being shared and through the case management process which would result in consideration of you know whatever the medical need is for those people.

With respect to the other question about state requirements, states are doing different things you know lots of the federal government is doing lots of things related to opioid, many states are doing things with limitations on prescribing, dispensing, and you know anything specific to a state would be outside the scope of what we do here at Medicare, but obviously you know pharmacist is going to have to adhere to whatever the laws in their jurisdiction are as well.

Janeen Glee-Bah: Okay, thank you.

Nicole Cooney: Thank you.

Operator: Your next question comes from a line of Maria Surratt.

Maria Surratt: Yes, thank you for taking my call. I wanted to know if there's going to be a new codes, rejection code issued by NCPDP to cover these edits and other outcomes.

Joanne Hilburn: I'm sorry, could you restate the question again.

Maria Surratt: Yes. I just asked you can build rejection code from NCPDP at the pharmacy at the point of sale, what they would get a rejection code I'm assuming to specify these new guidelines. Has that been addressed or is that forthcoming?

Joanne Hilburn: So are you asking about the rejection codes that are published by NCPDP.

Maria Surratt: The rejection codes at the point of sale in the pharmacist goes ahead and enters the prescription, would they receive a new specific rejection code that addresses the issues outlined.

Joanne Hilburn: Okay. So, if you are asking if there are specific transaction codes done by NCPDP and PBMs. So that information should have already been shared by the plans to you know individual pharmacies, a lot of plans indicated and PBMs have indicated that they have done fax blasts to educate individual pharmacies.

Maria Surratt: Okay, we'll go back to the drawing board. Thank you.

Operator: Your next question comes from a line of Kim Emmerson.

Kim Emmerson: Hi, thank you. I was wondering if you could clarify some conflicting information based on the presentation. On the slide for the 7-day and Care Coordination edit you specifically talked about coverage determinations, but on the opioid benzo concurrent edit and long acting duplicative opioid soft edit, you didn't mention anything about coverage determinations, and then as we got to slide 19, it reverted back to talking about coverage determinations for any opioid safety edit. Could you clarify in which situation and out of those four, the coverage determination process does apply them?

Beckie Peyton: Thank you for the question. A beneficiary always has the right to ask for coverage determination for drug they believe should be covered by their plan. So, we focus on the 7-day edit and the Care Coordination edit because those are, well all the edits we talked about are new. Those are, I think a little bit different than what we're used to seeing in the Part D space.

And they may be because for example the Care Coordination edit involves a consultation with the prescriber, it may be that more often it's not able to be resolved at the point of sale and that sort of where the coverage determination process comes into play.

So, the concurrent use edit, and the duplicative therapy edit are soft edits and we think that those really are going to be more, you know up to the dispensing pharmacy to decide whether they want to go ahead and submit the overrides for those. Thank you.

Operator: Your next question comes from a line of Ann Costello.

Ann Costello: When you say long-term care facilities, did you mean for it to be just skilled nursing or also assisted living.

Nicole Cooney: Give us one minute.

Lisa Thorpe: Hi, this is Lisa Thorpe again. So, for drug management programs, there is not an exemption for assisted living facilities. There is an exemption for facilities that dispense drugs to their residents through a contract with a single pharmacy, and so that would have to be determined you know by the plan during case management if the beneficiary resided in a facility like that. So -- but there is not an exemption for assisted living facilities per se from drug management program.

Ann Costello: Thank you.

Operator: Your next question comes from a line of Jennifer Humeniuk.

Jennifer Humeniuk: Hello, thank you. I have a question on slide 28. You mentioned that in addition to the right to appeal in that risk determination and the patient also has the right to request the coverage determination and I was wondering as part of a DMP, can you kind of differentiate when the appeal would apply versus the coverage determination.

Nicole Cooney: One second please.

Beckie Peyton: Hi, thank you for the question. Unfortunately, we don't have any of the appeals subject matter experts in the room today. You can submit that question to them directly and I'm going to give you the resource mailbox address, it's PartD_appeals@cms.hhs.gov, just one more time PartD_appeals@cms.hhs.gov. Thank you.

Operator: Your next question comes from a line of Leann Lewis.

Leann Lewis: Hi, it's me again. But I was just going to address the question that someone had stated earlier about is NCPDP doing any new reject codes? There is extensive guidance on the NCPDP public website under resources, HIPAA information, and telecommunications version D.0 editorial guide, if you have any questions about it you can contact NCPDP on it, but there is documentation available outlining the scenarios and the reject codes available. That's all.

Nicole Cooney: Thank you very much.

Operator: The next question comes from a line of Diana Yay-Zel.

Diana Yay-Zel: Hi, I was just wondering from the clinic level, how do we start prior authorization?

Beckie Peyton: Hi, if you're referring to situation with one of the safety edits, and there's no resolution at the point of sale or again you can do that prior to the prescription being presented at the pharmacy. The prescriber can

request a coverage determination on behalf of their patient, and you can do that, that includes prescriber office staff. So, you would do that through contacting the plan either over the telephone or in writing. Plans are required to accept coverage determination requests verbally.

Nicole Cooney: Nicole, do we have another question.

Operator: The next question comes from a line of Lucy Marini.

Nicole Cooney: Hi Lucy, did you have a question?

Lucy Marini: Yes. I'd like to know if you can tell me how the discussions that we had today relate to the MIPPS measures and the bonus points for PDMP.

Nicole Cooney: Hi, we actually don't have anyone in the room that can address questions related to the quality payment program that's not one that we had anticipated, but you can reach out to them at QPP@cms.hhs.gov and they may be able to address your question for you.

Lucy Marini: Okay, thank you.

Nicole Cooney: Thank You

Operator: As a reminder in order to ask an audio question, please press star followed by the number one on your touch tone phone.

Your next question comes from a line of April Shaw.

April Shaw: Hi, this is April Shaw in Congresswoman Betty McCollum's office. I had a question, it sounded like from the presentation that the Drug Management Programs are a result of the CARA Act of 2016, and so I just wanted to see if I'm correct in understanding that and then is it that the safety edits or result of the CMS road map or if you could just clarify where these two policies came from. Thank you.

Lisa Thorpe: Hi, this is Lisa Thorpe again. So yes, the drug management program that were finalized, the provisions that were finalized in the final rule last April were a result of the provisions that were enacted in CARA.

Michelle Ketcham: Right and this is Michelle Ketcham and I can address your second question. Part D sponsors are required to have effective drug utilization management and quality assurance programs that's been a requirement since our program began and as you'll see our policies have certainly evolved especially at point of sale and the utilization of safety edits as an important tool and lever to identify and address opioid over utilization.

So, over time, we've had certain policies where we expected sponsors to implement safety edits around MME and then as we have been observing you know what been going on with the opioid epidemic as well as considering the CDC guidelines and other resources and additional best practices going on across the nation.

We identified some additional policies that you know we implemented for this year. So, it's really under the umbrella of either requirements or drug utilization management, quality assurance, the expectation that sponsors

have concurrent drug utilization review, mechanisms to address over utilization of prescribed drugs, particularly opioid you know considering the opioid epidemic.

Nicole Cooney: Thank you.

Operator: To ask a question, press star one, star followed by number one on your touch tone phone. To remove yourself from the queue, press the pound key.

The next question comes from a line of Heather Johnson.

Heather Johnson: Yes, this is Heather Johnson and I'm from a clinician's office. This is a follow up question to the -- how to start a prior authorization. We had issues with a patient comes in and we have their Part D card. However, the numbers on that card are not the company that's represented on that card. And therefore, were chasing a trail trying to find the correct numbers to get that prior authorization started, do you have any suggestions or a resource that we can go to.

Michelle Ketcham: Hi, this is Michelle Ketcham again. I think your best resource is to contact 1800 Medicare. They should be able to assist you on the beneficiary and understanding the correct contact information at the plan level.

And there's also are you aware of the regional office resources? You know there are different regional offices in the nation to specifically address these beneficiary issues, so hopefully one of those can get you in the right direction.

Heather Johnson: Thank you.

Operator: Next you have a follow up question from a line of Jennifer Humeniuk.

Jennifer Humeniuk: Hi, thank you. On slide 24, you mentioned that for pharmacy limitations before implementing the limitation the plan must verify with the prescriber that the patient is at-risk, but it's not required to obtain the prescribers agreement to the limitation.

From my recollection of the final rule, I thought there was a—I guess disclaimer to that if no prescriber was responsive, the plan could still implement a pharmacy limitation, so could you please clarify that.

Lisa Thorpe: Hi it's Lisa again. Yes that's correct if during case management, the plan is not able to make contact with any of the prescribers and there's certain parameters set forth in the final rule and in our guidance about the efforts that have to be made to do so, but if they aren't able to they do have both the beneficiary specific claim edit, so they can implement as well as the pharmacy limitation, but they cannot obviously implement a prescriber limitation without contact with that prescriber.

Jennifer Humeniuk: Great, thank you.

Operator: Your next question is a follow up question from Linda Siy.

Nicole Cooney: Did you have a question for us?

Linda Sigh: Hello, can you hear me?

Nicole Cooney: Yes.

Linda Sigh: Hello. Okay my question was also regarding slide 22, where it talks about the drug management program tools and limiting access and it says you know and it give these options a patient could be required to only get their prescriptions from a specific prescriber or pharmacy or limits could be placed on the amount of drugs that could be dispensed. Who makes that determination on which one of these tools or which one of these restrictions are put into place and then who also makes determinations on the amount of the specified drug?

Lisa Thorpe: Hi, it's Lisa Thorpe again. So the plan makes that determination based on case management, and in the context of a beneficiary specific point of sale edit, the desired result is that is in consultation with the prescribers as to what the medically necessary amount is, but if the plan is not able to get a response from the prescriber, they can't implement one.

**POST CALL CLARIFICATION: This above sentence should read "The plan can implement one."**

However now that they have additional tools available to them through the drug management program such as the pharmacy limitation, they can put a pharmacy limitation in place and again you know the beneficiary has an opportunity to pick the pharmacy, so we expect that plans would be more likely to use that limitation at least first to resolve the case rather than a beneficiary specific edit in cases where they're not able to contact a prescriber, have case management with the prescriber.

**Post CALL CLARIFICATION: To further clarify, this statement should read:**

**However now that they have additional tools available to them through the drug management program such as the pharmacy limitation, the plan can put a pharmacy limitation in place and again you know the beneficiary has an opportunity to pick the pharmacy, so we expect that plans would be more likely to use that limitation at least first to resolve the case rather than a beneficiary specific edit in cases where they're not able to contact a prescriber, meaning have case management with the prescriber.**

Linda Siy: And to clarify, this would also include your benzodiazepine drugs for 2019, not just opioids?

Lisa Thorpe: Correct.

Linda Siy: Okay.

Nicole Cooney: Thank you.

Operator: And with no further audio question, I will hand the call back to Nicole Cooney.

## Additional Information

Nicole Cooney: Okay, thank you. Just as a reminder the audio recording and written transcript from today's call will be available in about ten business days on our call web page and we will also announce their availability in the MLN Connects newsletter. All registrants will receive an email to evaluate today's call. We hope you'll take a few moments to tell us about your experience.

Again, my name's Nicole Cooney and I'd like to thank our presenters and also thank you for participating in today's Medicare Learning Network call on the New Part D Opioid Over Utilization Policies. Have a great day everyone.

Operator: Thank you for participating in today's conference call, you may now disconnect.