>> Good morning. So, we're going to get started with the segment entitled, Part D Event Derived Files. What I'll be talking about is why derived files were needed or why they were created, who creates them, and then which variables in your PDE data are derived and how they are derived. Again this first slide just gives you some of the acronyms that I'll be using in the section.
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So, why are derived variables needed? Marshall briefly touched on this yesterday morning but when the Part D Federal Regulation took place, CMS took additional steps to safeguard the beneficiary's privacy as well as the pharmacy, the prescriber, and the plans what's considered commercially sensitive data. So, because of that researchers by law are not able to link the PDE data to other outside data files such as those landscape files that Marshall talked about yesterday and because of that, information has a lot of good information that Kyoungrae will be talking about today regarding maybe about the pharmacy, the formulary, or pricing about the plan, the benefits that the plan has, that's why we have created some derived variables as well as some characteristics files that Marshall touched on as well. So, CMS will allow this data to be linked to these other characteristics files but not to other databases so they can--we'll not use send you these identifiers for data leakage purposes.

One of the other things that has to be derived because the plans consider it commercially sensitive information or proprietary information, when they send their information, if you look at that PDE record layout the plans actually submit the gross drug cost in three separate variables specific to ingredient cost, dispensing be in sales tax. But again, those were considered commercially sensitive variables so you will never see those in your PDE data, so that is will also be aggregated for researchers. However, please note that beginning in 2010, vaccine administration fee is also included and that gross drug cost that is because typically a lot of pharmacies are just giving shingles vaccines or flu vaccines, and things like that. So, that's getting included in the gross drug cost and I'll be touching on that a little bit more next segment.

So, who derives them? It is Buccaneer, CCW, that creates these derived variables to include in your PDE data for research purposes and the six variables that I'm going to talk about that are the derived variables are the gross drug cost, the benefit based, the prior authorization, indicator for Medication Utilization Management. A tier, if there's any quantity limit to the drug and if there's any step therapy to the drug. So, where to find these derived variables? When they first started out, you will find all of these derived variables in the 2006 to 2009 file. If someone had gotten the data prior to that time be aware that all of these derived variables are actually in the PDE event record. However, when they created a formulary file in 2010 they moved the utilization management variables to the formulary file because they are all based on the plans formulary. So, what remained in the actual PDE event record is the gross drug cost and the benefit based. However, if you are interested in those utilization

management 2010 forward, you would have to request the formulary file.
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I just want to remind you about the standard benefit. I wanted to just really touch on the 2010 data benefit because I'll be giving examples based on this because that is the last year of data that we have and have been working with the 2011 data is currently out. But a lot of what I'll be touching on is based on the 2010 benefit. So, I just--we wanted to remind you when I'm talking about the benefit based that there are the phases where the beneficiary is first in the deductible. If they have a deductible, keep in mind some plans offered no deductible. Then there is the initial coverage limit here where the enrollee pays 25 percent. The plan is responsible for 75 percent. Then at this time, there was still the--what we're going to call the donut hole where there was the coverage gap, and then catastrophic phase if they make it through the coverage gap. So, because a lot of people are very interested in and people moving to this different benefit phases of the standard benefit or what the benefit that they happen to have with their particular plan, but because you cannot link to the landscape file that gives the specific benefit information for that plan, you only have an encrypted plan ID no way to know exactly who that plan is. The CCW does create the benefit phase, the data sources that they use for that benefit phase is the Part D enrollment day which is the plan that the beneficiary selected so they know specifically which plan that benefit that beneficiary is in.

And then they use something called the CMS Health Plan Management System, the HPMS. That is where all the plan information, all the benefit plan information is stored. And so, it has information like what type of organization it is including plan type, whether it's a demo, so on and so forth as well as the specific benefit structure they have. In other words, is it just at standard benefit that the plan offers? It also includes information about what deductible that plan has, what their initial coverage limit in any kind of out-of-pocket threshold for the specific plan benefit. And then lastly they'll take information from the PDE data that's primarily accumulating all the cost for the beneficiary using the gross drug cost as well as calculating the True Out-Of-Pocket cost.

So, how does CCW derive the benefit phase? For each beneficiary they will sort all their fills, their drug events in service date order. And then what they will do is look at the gross drug cost and the True Out-of-Pocket Cost and they will accumulate for each one of them. Now, when they then calculate where that fill took place in which benefit, they only do it for covered Part D events. So, if a beneficiary is in the enhanced plan and that drug happens to be an enhanced drug that will not have a benefit phase associated with that fill because benefit is what we calculated for covered Medicare drug events. So, what they will then do is accumulate the gross drug cost and compare it to the deductible. The ICL, the Initial Coverage Limit and then the TrOOP Cost for that particular plan and compare it to the out-of-pocket cost that are assigned to that particular benefit value, phase value. There happens to be two digits. It's a two digit variable.

It get--the first one will tell you where that fill was at the start of that fill and then the second one is at one phase that beneficiary would be after that fill. So, you can have fills that will jump phases. If it's a very expensive drug, it may go right from the deductible into possibly the coverage gap. I know there's some biologics that are very expensive and with one fill you can, you know, really get pass a lot of these phases. But it has both of them where that fill started and where it ended. And just note that for some again there'll be blank benefit phase information for any record that was not a covered drug. And again to verify that it was not a covered drug you can look at that drug coverage status code variable. If there is an XX it means that the PDE record could not link to the planned characteristics file to find out what the benefit was for that plan. And then also there are some N/A. It's not applicable because has-- Kyoungrae talked about yesterday there some plan--all right, excuse me. I guess it was Marshall may have been that there are some plans that do not report benefit information they're not required too. But the rest of them then just reflect whether or not they're in the deductible phase and then that second variable for the other phases, the ICL phase and then pre-ICL, ICL, and then the coverage gap, and then the CC stands for catastrophic phase. When you look at the benefit of phase, these percentages are based on fills not beneficiaries that fell into these phases.

^M00:10:00 But I just kind of gave you an indication that for those that reached that had fills within the coverage gap, it is starting to go down from 2008 through 2010 a little over 18 percent down to almost 16 percent for those got into the gap. And then similar pretty flat line, but it is going down a little bit then as far as how many fills go through the coverage gap and in--up in the catastrophic phase.

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[Inaudible Remark]
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This is per fill.
>> OK, [inaudible].
>> So this not how many beneficiaries ended up in the gap. Marshall said about 10 to 11 percent beneficiaries themselves. I just counted the number of fills that were covered in each of the gaps.
>> The percentage of the fill.
>> Yes, yes.

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But when you are looking at the benefit phase of variable, keep in mind that there are some considerations that you have to think about not all beneficiaries used. PDEs, they don't all have PDE records. And then, keep in mind too that some plans are not required to submit their benefit structure. So, I believe you lose about three percent of beneficiaries or fills because their plans are not required to submit benefit information and not all the plans offer the standard benefit. So, if you are interested in where beneficiary is, you do need to get this variable because the CCW

links to that beneficiary specific plan and some plans have more generous benefits than others. So, if you know--just because you know what the standard benefit is they can--I can calculate this myself, it may not be accurate for that specific beneficiary. So, this--is this--if this is of interest to you, you definitely need to get the phase variable--excuse me.
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And again just to reiterate those that have a drug coverage status of E which stands for an Enhance Drug or an O which is Over-the-Counter Drug, the benefit phase will be blank for those fills. Any questions about the benefit phase? OK, I'm going to--I'm going to talk about those Medication Utilization Management Variables. Again they are derived as well. For those that are interested in whether or not that fill is subject to utilization management tools, you might want to know this. It is derived from the formulary files develops some--has some benefit information for the plan as well. So, the quantity limit, again that just means that the plan has limited the number or amounts of a drug in a given period of time. Ambien may be a perfect example where they want to be sure that you're not abusing it or maybe I've tried to--try to renew of other, some pain killers may also fall into quantity limits that they're only allow so many fills for particular drugs. So, if that's what interest to you to see did this person no longer get this drug because there was a quantity limit to it, you may need to get the formulary file beginning in 2010 or it will be in the PDE data prior to that. Prior authorization, there are also some drugs that require prior authorization before it will be covered. So, that may take an additional step and you may want to know about that.

And again step therapy. What this variable just tells you is what the maximum step is. Again, a lot of plans will to say that, "Well, let's try this drug before we move you onto a more expensive drug." That is often times why you will see some over-the-counter drugs in the data file is a Prilosec is an often over-the-counter drug you may see simply because that may be the first step if someone has GED before they give you a prescription. So, they may try some over-the counter-drugs prior to prescription drugs and step therapy.
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For these variables it is product specific information within the plan. So, again it takes the information from the formulary as well as looking at their benefit. And so, if you are interested in examining whether the level of utilization is specific for that medication is influenced, you will want to get these management tools. Again, that the prior authenticator, the tier, many of you may be concerned, well is this a brand drug, is this a generic drug, what tier is it on because that may determine what the coinsurance is what their co-pay is, does that influence drug choice quantity limit step number? Again, the data sources are the HPMS or that health plan management system which stores the plans benefit information. So, they have the specific plan and benefit package

information, they also use the plan formulary. Now, keep in mind that sometimes it may have a little bit of a disconnect. If you link it to the plan ideas because when CCW derives this information, they use the end of the year snapshot information that is in the HPMS specific to their formulary and specific to their benefit package. And sometimes plans can change some of those--some of that information throughout the year particularly the formulary may change throughout the year. So, they just use end of the year snapshot. So, it may not be accurate as to what that point of service tools was, so I just kind of keep that in mind that when they derive these fields.

And again just to reiterate that CCW isn't always able to match all event record, so, very similar to the benefit phase you will find some N/As or XXs [phonetic]. Again it means that they were not able to link to the formulary or unable to link to the plan. And again depending on the year it's pretty stable between three and half to four percent of the records are not able to link.
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So, looking specifically at the prior authorization indicator values it's just a one that yes the drug is a subject to prior authorization or a zero, it's not or that there are no restrictions on the drug in the formulary. When you look at the variable itself only about a little over one and half or excuse me one in a quarter percent of the actual PDE records of fills are identifying--are identified as needing prior authorization. The tier values is just one to a max number of how many tiers that that plan happen to have in their plan package. So, again it just designates whether or not there is a Tier ID assigned to that particular fill.

If you look at it this is just--again these percentages might change from year-to-year depending on the year of data you're looking at. But most of them only have one to maybe three tiers in their benefit package, after that it drops off pretty significantly. I think you can get up to high as maybe seven or eight, or nine even but it really drops off significantly after the third tier. For the quantity limits again it's just a yes, no. Did the drug have quantity limits? And then zero means either it didn't, or the plan doesn't submit a formulary so, there's no restrictions on the drug. When you look at the fills in the file, there're about 25 percent of the records that did have quantity limits.
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Lastly, for the maximum step values, again it's either blank that there is not--it's not part of a step therapy group or it's not restricted. And then the numbers itself will go from to the max, the maximum step on the plans formulary that is associated. Again, this is a variable that is not very frequently populated approximately 94 percent of the fills in the PDE five percent file were blank.

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If you're interested in learning more about some of these derived variables a CCW does have Part D information user guide and I've given you the URL for that as well as if you want more detail you can always look at the guide for the Medicare Part D Prescription Drug Event Data and that's also there.

OK, so the question is just visually when I get the PDE data is there just one file or there is several files? So, for the actual PDE record itself it's just one file, and then if you request the Drug Characteristics file which is an additional "file" that you have to pay for but they actually append that information on the PDE record. So, a Drug Characteristic file and PDE event record will be in the same file, on the same record. If you're interested in getting the formulary file, that is a separate file that has specific variables within the PDE record that would be used to link to that file. It has a formulary ID, likewise the Plan Characteristics file is a separate file and it actually has four files into that that Kyoungrae will describe. But that's just one file that you would purchase that has several files within it. And then the Prescriber Characteristics file is a separate file, as well as the Pharmacy Characteristics is a separate file.
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And I'll be talking about those two this afternoon as well.

So, the actual--if you want to know about characteristics of the plan, the pharmacy, or the prescriber those would all be separate files. If you want the drug characteristics so as would be contained in the PDE event data. Right. Because over-the-counter drugs are not covered unless it happens to be either an enhanced plan that maybe offers it for some reason will allow it to be offered has a--within their formulary or it typically is found because of its four step therapy. But, I'll be talking about over-the-counter. I believe I--well, I apologize. I don't remember if I already told you what the percentage was. But I think there's only like 0.02 percent of the fills that are over-the-counter. It's a very small amount. So, you don't--you cannot study over-the-counter drugs if that if--
>> The drug.
>> Yeah, if that's where you were going with that, the question is can I study over-the-counter drugs, and the answer is really no.

Right, so the question was when we look at the benefit phase is that related to an actual prescription fill? The answer is yes.

[Inaudible Remark]
Good question. So, let's say I am someone that has got into the coverage gap and I can't afford it, so then I go outside and go to Walgreens and get my, you know, four dollar fill for that. That information does not get in. So, you have to stay in your Part D program in order to get out of the coverage gap and go through. Now, keep in mind again anyone who was an LIC as low income subsidy beneficiary, they typically don't have

covered--they don't have coverage gap issues as well as there's a lot of--when you were looking at those plans, some of the benefits of some of these plans were that we will cover--you in the coverage gap. So, there's not a lot of people in there, but in order to get through the coverage gap, you actually have to have it submitted through the Part D plan and not outside of it to get it through.