CENTERS FOR MEDICARE AND MEDICAID

Special Open Door Forum on Medicare Part D Claims Regulations

Conference Leader: Abby Block
Moderator: Natalie Highsmith
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Operator: Good afternoon. My name is (Rebecca) and I will be your conference facilitator today.

At this time, I would like to welcome everyone to the Centers for Medicare and Medicaid Services Special Open Door Forum on Part D Claims Data Regulations.

All lines have been placed on mute to prevent any background noise. After the speaker's remarks there will be a question and answer session. If you would like to ask a question during this time, simply press Star, then the number 1 on your telephone keypad. If you would like to withdraw your question, press the Pound key.

Thank you Ms. Highsmith. You may begin your conference.

Natalie Highsmith: Thank you (Rebecca) and good afternoon to everyone and thank you all for joining us for a Special Open Door Forum on Medicare Part D Claims.

CMS is hosting a Special Open Door to discuss the recently published Medicare Part D Claims Data Rule allowing federal and state agencies and qualified researchers access to Medicare Part D data.

Senior CMS officials and staff from our Office of Research, Development, and Information, the Centers for Beneficiary Choices, oh I'm sorry, the new name for CBC is the Center for Drug and Health Plan Choice and the Office of Information Services will discuss the rules, the process for requesting Part D Claim Data and will listen to your comments and answer your questions.

I will now turn the call over to (Abby Block) who is the Director of the newly named Center for Drug and Health Plan Choice. (Abby).

(Abby Block): Thank you. I want to welcome everyone from the research community, government agencies, and other interested parties to this audio conference on the recently published Medicare Part D Data Rules.

As a result of this rule, information on Medicare drug claims for the 25 million Medicare beneficiaries in the Part D Plan, may be linked to Medicare claims for hospitalization and physician services. With the ability to make this linkage, we now have an unprecedented tool for evaluating, not only the Medicare Prescription Drug Program, but the entire Medicare Program and by extension we'll be able to look at the well being and health care of millions of Americans.

Information on Medicare drug claims will be of tremendous value to us in CMS, as we run the Medicare Prescription Drug Program. Now we will be able to use the data for many purposes beyond payment including program monitoring, care coordination, and quality improvements.

When the Secretary announced the release of the Medicare Part D Data Rule on May 22nd he also announced one of its most important uses, to address public health and safety issues. As part of the FDA Sentinel Initiative, CMS and the FDA will analyze information on Medicare Part D claims as part of a broad effort to insure that the medications we take are, not only effective, but also safe.

Over time, use of the Medicare data will help to improve medical care for all Americans. These data will be critical in identifying adverse drug events. The IOM estimates that about one and a half million preventable adverse drug events occur each year in the United States.

A study in (JAMA) found that about 530,000 preventable adverse drug events occur each year among outpatient Medicare beneficiaries. The cost to Medicare of treating these preventable events is estimated about $887 million every year. With the information we'll gain from research using Medicare claims, we anticipate that there will be fewer of those adverse drug events over time.

Researchers at NIH tell us that they're very anxious to be able to use information on Medicare Parts A, B, and D claims data in their studies on cancer, heart disease, kidney disease, and strokes. These data will allow them to track individuals over time and to access both short term and long term treatment effects that may not be captured in clinical trials because of the small number of cases or because a health event occurred beyond the period of the trial.

It's clear that information on Medicare Part D claims will be of enormous value to all Americans as CMS and our sister agencies at FDA and NIH and

many researchers outside of government make use of it to improve medical care.

Probably CMS' most difficult challenge in creating the Medicare Part D data rules was striking the right balance between making information on prescription drug claims available to researchers while protecting individual privacy and preserving the underlying competitive structure of the Part D program.

We believe that after many months of work and careful review, we do have the right balance. We'll be covering a lot of information today on this Open Door Forum.

Our next speaker, (Nancy De Lew) will give you an overview of the Part D data rule. (Nancy) is with the Office of Research, Development, and Information, otherwise known as ORDI. She will describe our policies and the special protections associated with the release of Part D claims information.

Following (Nancy), (Penny Mohr) from ORDI will walk us through how researchers may use Part D claims information and also provide some general ideas of what kinds of studies may be done with the data.

(Penny) will be followed by (Dan Waldo), also from ORDI and (Dan) will be going over some of the finer points of the data and will also talk about some of the supplemental information that will be developed later by CMS to enhance a researcher's ability to use the data to answer particular kinds of research questions.

And finally, (Spike Duzer) also from ORDI, will discuss the data release process and introduce the CMS contractors who will assisting all of you in submitting requests for Part D data.

After that, we'll be happy to take your questions.

Again, I want to thank you for joining us on the call today. I hope that you'll find this information informative and worthwhile. And now I'd like to turn the microphone over to (Nancy) so that we may begin the discussions.

(Nancy Delou): Great. I'm happy to be here to tell you about the provisions of the final rule. Before I do that, I want to review quickly the history of the rule and how it came to be a final rule.

First, we published a notice of proposed rule making on October 18th of 2006. We proposed in the (NPRM) to treat Medicare Part D claims data in a similar manner to how we treat Medicare Part A and B claims now. We invited public comment on whether we should consider any additional protections for beneficiary privacy or commercially sensitive plan data.

We received a number of comments on the rule, most of which supported treating Part D data similar to how we treat Medicare A and B data. But we also received some comments requesting more protections for beneficiary privacy as well as commercially sensitive plan data.

In response to the comments, in the final rule we published on May 28th which will be effective on June 27th, we added additional protections for beneficiary privacy and commercially sensitive plan data.

As (Abby) noted in her remarks, our goal is to strike a balance between making data available, for public health and safety, for research, and the other purposes you'll hear about today, but we wanted to do that in a way that protects beneficiary privacy and commercial sensitive plan data.

To that we're taking a number of steps, one of which is that we will provide the minimum data necessary for a project. For instance, in a study of drug safety issues, the project likely wouldn't need cost elements, so we wouldn't be providing cost elements.

To the extent feasible, we're going to link data at CMS, so that we don't need to send real identifiers to parties outside of CMS. That will help us protect beneficiary privacy and plan, prescribers, and pharmacy identifiers.

Where we do need to send identifiers, for example, to link to another data set, we will encrypt the identifiers during transmission. We'll provide a link key to let the researcher identify the real identifier. We'll allow for data linkage and then we'll require that the data be re-encrypted so that if a last top is lost, for instance, we don't have important data falling into the wrong hands.

We're also going to roll cost data up to an aggregated amount on each claim, so we'll have ingredient cost, dispensing fee, and state sales tax aggregated for each claim and our purpose in doing that, is so that dispensing fees are not available separately to external researchers.

We've got more information about this topic in the appendix to the final rule. We have what we call a data availability chart at the end of the rule. We also have it at the end of the fact sheet, which is available on our Web site and the link to that is on the Open Door Forum page.

I want to underscore that the final rule covers Part D claims. It does not cover Part D plan bids, rebates, risk sharing, or reinsurance data. There was some confusion about that in the comments that we received on the NPRM and we have received some questions about that since the final rule was published this summer.

So I want to be very clear, the rule only covers the information on Part D claims. The claims data elements themselves are on the Web site and they'll be reviewed in more detail in a few minutes by (Dan Waldo). The rule doesn't cover the Part D plan bids, rebates, risk sharing, and reinsurance payments, as just noted.

Those are considered to be commercially sensitive, the release of which could potentially affect competition and potentially increase prices to tax payers and beneficiaries. They continue to be protected and they are not available under this final rule.

So I want to talk a minute about Part D data. Who can get it and for what purposes? In the preamble to the final rule, we discussed at length who can request the Part D claims data and for what purposes. I'm just going to summarize at high level that information here.

First, federal agencies can get Part D claims data for research, program oversight, drug safety, and other purposes. We've had numerous requests from federal agencies, including the FDA and NIH, as (Abby) noted a few moments ago, as well as the congressional support agencies, the congressional budget office, GAO, MEDPAC, and other federal agencies.

In addition, state agencies have requested Part D claims data. They have asked to use it for their work for care coordination and disease management for their

dual eligibles. We'll be working with states to discuss with them their requests for the Part D claims data.

Third, we've had a number of researchers request Part D claims data for a wide variety of studies. (Penny Mohr) is going to be telling you more in a few minutes about the kinds of studies we think the external researchers may want to do with the claims data.

Fourth, commercial entities have asked for direct access to the Part D claims data, but we're modeling our Part D data release policy on what we do now, under the HIPAA privacy rule for Parts A and B data.

Under the HIPAA Privacy Rule, what we allow now, is for a commercial entity to fund an independent researcher at a university or a non-profit as long as that research is conducted independently and the results are in the public domain, whether or not, they're favorable to the sponsor.

So to further meet the needs of commercial entities, we are going to be developing a public use file, which commercial entities and others could purchase like any other member of the public.

(Dan Waldo) will discuss in a few moments our plans for the creation of a public use file. We're going to be soliciting input from the public about what would be useful in such a file.

As (Abby) noted, at CMS internally, we have a number of uses for the Part D claims data. Some of our uses include program oversight, research, demonstrations, evaluations, plan performance measures.

As many of you know, we haven't been able to use the claims data to date for other than payment purposes. Once the rule is effective at the end of this month, we will in CMS use the claims data to develop some basic descriptive statistics about the program.

We're going to be publicly reporting information such as the top 100 drugs that beneficiaries take, how many beneficiaries reach the coverage gap, how many reach catastrophic coverage, etc. So we will be reporting on these and other topics over the course of the next few months.

One other thing to note about Part D data in terms of what it is, we have drug claims for Medicare beneficiaries who are in a Part D plan. We do not have drug claims for Medicare beneficiaries who receive their drug coverage from another source, be that the VA, the Medicare Retiree Drug Subsidy, or other insurance sources.

In 2008, when the program is fully operational, we have about a billion claims. In 2006, the first year of the program with open enrollment, as many folks know, it was extended until the middle of May. We don't have a full year of claims for many of those beneficiaries, because they didn't sign up early in January. Some folks signed up later on in the year and (Dan) will talk more about some of the limitations of the data that's available for the first year of the program in a few moments.

So I'm going to turn the program over now to (Penny Mohr) from our research office is going to talk about the data.

(Penny Mohr): Good afternoon. I'm Director of the Division on Research and Health Plans and my division has the responsibility of conducting research on evaluations

of Medicare Parts C, also know as Medicare Advantage, and Medicare Part D, or Prescription Drug Benefits.

The prescription drug benefit has been a remarkable advance for Medicare. It's now about 90% of beneficiaries with prescription drug insurance compared with two thirds of the beneficiaries that did not have drug coverage in 2006.

But with this momentous expansion of the Medicare Program, comes the responsibility for us at CMS as stewards of the program and for you as outside researchers whose critical skills we need to examine the financial, health, and access implications of Part D.

Coupled with other administrative data, the prescription drug event data go a long way towards helping us understand how beneficiaries have been impacted under Part D. These data will help us gain an understanding of the most basic mechanics of the Part D program, such as how many beneficiaries reach the coverage gap.

Remarkably, until these data were made available, we were unable to answer even the most basic of questions.

As my colleagues will address next, we plan to append plan features from our chronic condition warehouse to the PDE data, such as whether the plan offered coverage in the gap or whether they offered it a standard benefit or an enhanced alternative benefit.

This augmented data set will enable a researcher to address a whole host of questions. For example, does a specific benefit design contribute to favorable or adverse selection into drug plans? What is the effect of switching among

drug plans on drug use and out-of-pocket spending? How does patient cost sharing influence the patterns of drug use and adherence?

We also plan to append beneficiary enrollment characteristics to the file, such as whether they qualified for a low income subsidy, what level of subsidy, and if they were duly eligible for Medicaid and Medicare. This will allow a researcher to examine how special populations, such as dual eligibles faired under Part D.

For example, how does Part D benefit design compare with their former Medicaid coverage and how this impacted the use of drugs? Linked with A and B data, the PDE data will afford researchers a more complex understanding of the effect of the drug benefits on spending in other parts of Medicare.

One hypothesis is that improved access to medications could avert costly hospitalization or slow the progression of disease. As we will be able to follow beneficiaries over time, these data will now allow us to address such questions as does improved access to oral anti-diabetics reduce long term complications of diabetes?

As (Abby) mentioned in her opening remarks, the importance of these data for providing a comprehensive view of the treatment of specific diseases. To take cancer care as an example, in recent years there's been a significant rise in drug costs as a component of cancer care and more elderly are being treated with chemotherapy.

Although chemotherapy has traditionally been covered under Medicare Part B, approximately 25% of cancer drugs in the pipeline are oral and would be

covered under Part D, rather then Part B. Oral cancer drugs are expected to have an increasingly important impact on the drug benefit.

PDE data will enable us to have a more comprehensive view of cancer care and the interface between Part D therapy and those provided under Part B. With the PDE data we will be able to examine coordination of care issues that may arise with overlapping drug coverage.

The PDE data will also help support the President's Initiative on Health Care Transparency. CMS has developed performance and quality measures to insure that Medicare beneficiaries have the data necessary to make informed decisions in order to receive the best health care and prescription drug coverage available.

Part D plan ratings are currently available on the Medicare Prescription Drug Plan Finder. The PDE data will allow us to enhance these measures. For example, we have near term plans to develop, test, and validate patient safety benchmarks. Ultimately, these measures will help our beneficiaries make informed choices about their drug plan.

In addition to helping CMS address questions to improve the program, the data provide a wealth of epidemiological information to better understand the nature of patterns of drug use among the elderly and disabled and their effects on health and safety.

As many of you underscored when you commented on our proposed regulations, today our knowledge of pharma therapy in the elderly or disabled populations has been very limited. Often the very old patients with multiple chronic conditions and those taking multiple medications comprising the vast

majority of the Medicare beneficiaries are routinely excluded from clinical trials required for FDA approval.

Even when clinical trial data exists on efficacy for this population in the selected site, results may not generalize or provide information on effectiveness from a broad range of clinical settings from which beneficiaries receive care.

The FDA Sentinel Project that (Abby) mentioned, will make use of this unparalleled resource.

The Agency for Healthcare Research and Quality also has a mandate authorized by the same legislation that brought the Medicare Prescription Drug benefits to improve the quality and effectiveness and efficiency of health care by sponsoring comparative effectiveness research.

This mandate clearly was intended to enhance the Part D program as AHRQ is required to disseminate findings from their research to Part D drug plan sponsors. The availability of the PDE data will better enable AHRQ to insure the research they sponsor is relevant to Part D enrollees.

There's so many more questions these data can help us answer, that we cannot possibly get to with our limited resources and we need outside researchers, such as many of you, to help insure that we have the best program possible for our beneficiaries and that they have access to the most effective and safest drug treatment regimen.

Okay. Now I'm going to turn this over to (Dan Waldo) who's going to talk about the specific data.

(Dan Waldo): Okay. Good afternoon. Thank you very much. As (Penny) said, my name is (Dan Waldo). I'm an economist and data analyst in the Information and Methods Group in the Office of Research Development and Information here at CMS.

And I'm going to review for you very briefly this afternoon, the data that are being covered by this regulation for release, the restrictions on what will be released. I'll discuss briefly public use files and supplemental data. And then talk again briefly about the limitations of the Part D data that are going to be available.

Thirty seven elements of the PDE record are covered by this regulation. We don't have time today to go through them one by one, but specific details on each of these can be found on our Part D data Web site, the link to which is on the Open Door Forum page and you can also get to it by going to the cms.hhs.gov Web site and entering Part D data in the search box.

Roughly they fall into a number of different groups. The first group is plan information. There are records - there are fields on the PDE record that indicate the contract number for the plan and also the plan benefit package number.

Beneficiary information on the file include the age and sex of the beneficiary and their health insurance claim number and a plan card holder number. There's a field that indicates the identifier for the prescriber of the drug in the event and also the dispenser of the drug in the event.

In the event - for the event itself, there are some fields that indicate the internal control numbers, the methods of submission and so on. More importantly perhaps for research, the date of service and the date of payment

and the coverage data's for the event, that is to say whether it's a covered drug, whether it's a drug that's provided under the supplemental formulary of the - of an enhanced alternative plan, or whether it's an OTC drug.

For the drug itself, we will have a field on the NDC or other codes to identify the drug and a field that indicates whether this is a compound or a single molecule drug.

There are also fields for the quantity dispensed and for the day's supply.

Cost information for the event includes the event cost, the - I'm sorry, the ingredient costs, the dispensing fee, and the sales tax that's applied, if any, whether the event is an out-of-network event or is being paid for under a Medicare Secondary Payer status, whether the event occurred under, at, or over the out-of-pocket threshold, and if it occurred at the out-of-pocket threshold, the amount that applies to the under and to the over.

There are fields for patient pay and for the true out-of-pocket amounts that are associated with the event. Any low income cost sharing subsidy amount that's associated with the event, any coordination of benefits reductions associated with the event, and what the plan paid for the event, both a standard benefit and any amount beyond the standard benefit.

Now, I should emphasize that not all of these fields will be available with their native value. As stated in the regulation, the contract number and the plan benefit package number will be encrypted, if they're provided at all. Other identifiers will be encrypted on a case by case basis to protect beneficiary's privacy and to protect plans commercially sensitive information.

And in addition, many of the elements will fall outside the pale of minimum data necessary for any given request.

I need to spend a few minutes talking about this minimum data necessary, because it's going to be important for people who are submitting a research plan. Few research questions are going to require all 37 of the data elements that are covered by this regulation and to reduce the risk to enrollees privacy and the risk of plans commercially sensitive information, we will only provide those elements that are needed to conduct an approved research project.

(Penny) mentioned a number of research questions and let me give you a couple of examples. For example, do specific benefit designs contribute to favorable or adverse selection among Medicare enrollees? To address this question, will require PDE cost data and it will required linked A and B data, but doesn't require a specific beneficiary identifier, nor does it require a provider identifier nor a pharmacy identifier.

The research question does require plan characteristics, but it does not require a specific plan identifier and those fields that are not specifically required will not be provided in the data that are released.

Another example, does access to drugs vary by race and ethnicity? It would require beneficiary characteristics that are not currently on the PDE record, but would be supplemented. It possibly would require linked A and B data, but it does not, again, require a beneficiary specific identifier, such as the HICN.

It might require a pharmacy identifier, but not necessarily the native value of that identifier and it would require plan characteristics, but not necessarily require a specific plan identifier.

Clearly, the concept of minimum data necessary indicates that a research plan has to be very well thought through prior to application for data to avoid having to go back and reapply for a supplemental draw on the data set.

As I mentioned, many of the actor's identity, the plan identity, the beneficiary identity, the prescriber identity, the dispenser identity, are most likely going to be encrypted. In which case, information about them will be lost. For that reason, we at CMS are working to develop supplemental information that can enhance the PDE data and replace some of this lost information without compromising beneficiary's privacy or plans commercially sensitive information.

For example, we might be able to append the enrollee risk scores. We might be able to append the physician specialty type or the pharmacy type. We will be able to append things like plan characteristics, the deductible, the initial coverage limit, whether the plan as an MAPDP or PDP, whether it's a basic plan, an enhanced plan, or an actuarially equivalent plan.

For event characteristics we might be able to append information on whether there's utilization management attached to this drug, whether it's a tiered drug, and if so, on what tier?

In providing this supplemental information, we need to strike a balance between the amount of data that's provided and the nature of the PDE elements for the records that are being included in the data being provided.

For example, if detailed plan characteristics are included, it may be necessary for us to stratify the sample by plan, so that the simple - the sheer number of claims would not provide information on the plan identity.

I need to emphasize that we are just beginning to look now at the issue of supplemental information and that no decisions have been made on these data sets. For that reason, we welcome suggestions from all of you on what kinds of additional information will be useful, and I'll talk in just a moment about how you can get those suggestions to us.

The public use - I want to talk a little bit about the public use files as well. The data requests that we've been talking about require a research protocol, a reviewed protocol, and then a tailored draw on the PDE data, all of which can be time consuming and costly.

To help to offset the burden of applying for PDE data, we're exploring the potential to release some sub set of those data in a public use format, one or more files that are designed to help researchers with general types of research questions.

Our intent here is to provide anonymized data that can be used without a data use agreement and at a much lower cost then the tailored files that we've been talking about in an implied form. We at CMS are working on the specs for those files right now, but as with the question of additional information, we would welcome your input as to what might constitute a useful public use file.

To get these suggestions to us, we've asked the Research Data Assistance Center or RESDAC to serve as a point of contact for suggestions. Their Web site will soon have a link that allows you to make a suggestion both on public use files and on the additional information that we could add to the PDE record.

In your suggestions we would ask you to tell us what generic kind of research could be addressed by this and what kinds of data would be needed. CMS staff will make the final decisions on file content and on supplemental information, so I have to warn you that there are no promises implied or otherwise in our request for suggestions.

Finally, although it's widely believed that PDE data are the greatest things since sliced bread, I have to warn you that there are some limitations to these data that make them not as useful for everything that you might think.

For example, the universe of people. Not all enrollees have Part D. The Part D, the PDE data are going to exclude enrollees who are in a plan, a private plan with a retirement drug subsidy. It will exclude enrollees who have creditable coverage such as Veterans Administration, Tri-Care, Federal Employee Health Benefits. In the 2006 data, some of the state pharmacy assistant plans and so on.

And of course, the PDE data are going to exclude experience for people who don't have drug insurance.

The research that's been conducted so far shows that Part D folks are different from those not in Part D. They tend to be in poorer health. They tend to have higher Part A and Part B expenses, and they tend to be less well educated among other things, for example.

So that the Part D population is not fully representative of the Medicare population as a whole.

A second limitation is on the drug use. Even for those people who are enrolled in Part D, not all of their drug events are going to be captured by the data and our system.

For example, most non-covered drugs are excluded. Most OTC's are excluded. Prescriptions obtained through another third party, such as the Veteran's Administration are excluded and some classes of drugs that are protected by privacy laws will be excluded as well.

A third limitation is on linkages with other data. As (Nancy) mentioned earlier, eight million people are enrolled in MAPD's. Unfortunately, we do not have Part A or Part B data for these people, so that linkage with A and B data is going to be restricted to the 17 million who are enrolled in stand alone PDP's.

Fourth, the PDE record itself is not the same as the pharmacy claim, and so it can differ from the point of service information, due to things such as post transaction adjustments between the plan and the pharmacy for payment errors. Plan to plan adjustments for folks that were - that seem to be enrolled in one plan, but were actually enrolled in another. And Plan to CMS adjustments for some demonstration projects.

Fifth, and possibly the most important, 2006 was a start up year. So there's a fair amount of unusual activity related to the longer transition period, as (Nancy) mentioned the fact that not everybody signed up right away, we've got a lot of data that are out there, and our experience with any start up data is that it poses a fair number of challenges.

Because of the - because the rule is not effective until the end of this month, we at CMS have not been able to look at most fields on the PDE record and so

we really are not in a position yet to tell you what kind of data quality we've got and we won't for a little while.

But our experience with the A and B data from 1996, suggests that many stats after 2007 data are going to be a lot better then the 2006 data.

So let me summarize. There's a tremendous amount of information available through the PDE record, but not all that information will be available in its native form in every data release.

We're working to develop information that will supplement the PDE fields and we're working to develop public use files that will be available without a data use agreement. We welcome your input on what supplemental information and what types of public use files would be the most useful to the research community and I encourage you to visit our Part D Web site and the ResDAC Web Site from time to time to keep up to date with the progress that we're making.

At this point, I'll turn to my colleague, (Spike Duzor) who will talk about the process for obtaining the PDE data.

(Spike Doozer): Thank you (Dan). As (Dan) said, my name is (Spike Duzor) and I'm chair of the CMS Privacy Board. Today I'm going to briefly highlight two contracts that CMS routinely uses to disseminate Medicare Part A and Part B data.

These contracts have an extensive infrastructure that CMS can easily build upon to disseminate Part D drug event data. The first contract is the Chronic Condition Warehouse or CCW. Part D reg states that most data requestors will receive their data via the CCW.

As you may know, the Chronic Condition Warehouse was mandated by Section 723 of the Medicare Modernization Act, which was signed into law in December of 2003.

Section 723 requires CMS to establish a data warehouse that's patient based, as opposed to our normal way of producing and disseminating provider based data. The CCW links the separate provider based claims which are hospital inpatient and outpatient, physician supplier, (SNF), DME, home health and hospice and produces an individual patient profile.

The CCW also links assessments and patient enrollment information with the claim. Finally, the CCW was designed to include Part D drug event data to produce a comprehensive patient level record of Medicare transactions.

The CCW has multiple years of Medicare Part A and Part B claims and patient assessment and it's been disseminating patient level data for the last three years to the research community.

The current CCW contractor is the Iowa Foundation for Medical Care and this organization also furnishes Medicare claims including drug events to the Medicare's Quality Improvement Organizations. The existing CCW infrastructure will easily allow us to disseminate Part D event data to the public.

Starting on June 27th we'll start loading the approximately 850 million Part D event claims into the CCW. We estimate that that'll take about five months to complete all tasks associated with testing, loading, linking, and extracting the data.

We hope that the database will be fully operational on December 1st. At that time, the CCW will contain all 2006 drug event data as well as 2003 to 2007 100% of Medicare Part A and Part B and patient assessment information.

The CCW will be able to disseminate requests for just Part D data and will be able to link Part D to Part A and B. We plan to disseminate the Part D drug event data similar to the way that we have been disseminating Part B physician claims for the past ten years.

As you may know, there are approximately one billion Part B physician claims annually. Because of the size and privacy issues, CMS does not release the entire 100% physician database to any requestor. CMS does release the 5% sample of the database and accepts finder files from researchers which they can run against the entire database.

Consequently, a researcher can receive all physician claims for a specific medical condition, specific geographical area, or for example, patients participating in a clinical trial. We plan to disseminate a sample of the Part D drug events to researchers and other requestors and support finder file requests for specific cohorts of the population.

We're still investigating what's the appropriate sample size needed to support most researchers. But, for today's discussion, assume that researchers and other requestors could receive a 15 to 20% sample of Part D drug events.

When we finalize that number in the near future, we will provide that to you, but our goal is to provide an adequate sample size large enough to support most research projects.

We plan to price the Part D data similarly to the way we priced Part B data. We anticipate that this 15 to 20% sample of Part D drug events would cost about $20,000. As in the Part B process, this price covers the cost of producing the data and also covers CMS costs of reviewing, processing, and monitoring the data request.

Depending on the size of the customized finder files, the price could be less for many requests. Once again, these are only estimates and that we will, because we've not touched the data and once we get more involved, we will provide more accurate and detailed information.

The second contract I want to briefly talk about that CMS plans to leverage to help educate the public about Part D data, is the Research Data Assistance Center Contract or what we call RESDAC. CMS awarded a contract to the University Of Minnesota School Of Public Health in 1996 and for the past 11 years RESDAC has been assisting researchers in how to obtain and to use Medicare data.

Since RESDAC is university based, they're very knowledgeable on how to design and conduct research projects and the methods to educate the public. But for the last 11 years, RESDAC has also assisted CMS in developing data release policies and procedures in helping us implement patient confidentiality issues governing the Privacy Act and the HIPAA privacy rule.

RESDAC has also been assisting the CMS privacy board since its inception in 2003. RESDAC has an extensive infrastructure in place to support the research community and CMS plans to build upon this infrastructure to have RESDAC help us educate and disseminate the Part D event data release policies.

Currently RESDAC operates a comprehensive Web site that contains all of our data release policies and procedures. The Web site also contains a wealth of knowledge designed to aid researchers in using the data that include data dictionaries, record layout, technical papers, highlighting data anomalies and program statistics.

The RESDAC Web site is linked to the CMS Web site. Over the next several weeks to months, CMS - the RESDAC Web site will contain more detailed information outlining the process necessary for requesting Part D Drug Event data.

The Internet address is resdac.umn.edu. The next speech - the next speaker will tell you more about that Web site.

In addition to a Web site, RESDAC also maintains a toll free hotline staffed by six full-time staff. Most of the staff have been working with RESDAC for at least five years and the toll free number is 888-9-RESDA or RESDAC.

RESDAC routinely offers workshops where potential users can receive in depth instruction on how to request Medicare data. We plan to build upon that infrastructure and RESDAC will be holding Part D requesting workshops in August, September, and October.

The current process for obtaining Part A and Part B data is that the researcher first comes to RESDAC. RESDAC informs the researcher of the data release policies, advising them how to complete the necessary forms, and offers advice on what data’s needed to conduct a study and provides the researcher with an estimated cost of the database.

We ask researchers to submit their data requests through RESDAC. RESDAC reviews these requests, forwards them to CMS, and ultimately to the CMS privacy board.

Building upon that infrastructure, we're going to require all Part D data requests to go through RESDAC first. Then RESDAC, and the requestor will follow a normal process of requesting data, including submitting a comprehensive research design or a document outlining why they want the data and explaining how the data will be used and how the data will be protected.

The requestor will sign a Data Use Agreement and submit evidence of funding. For Part D requests, the researcher will also have to justify which of the 37 Part D drug event data elements are needed to support the project. RESDAC will assist the requestor in supporting these element by element requests.

RESDAC will not be judging the merits of the request, but they will be determining, whether or not, the requestor followed the guidelines and submitted a complete package.

Once RESDAC completes their review, they will submit the package to a new CMS Part D Data Policy Analytical Board to review the merits of the minimum data necessary request.

The Part D Rule requires this level of review in order to protect the confidentiality of certain commercially sensitive information.

Finally, after the Part D Work Group conducts its review, some requests may be referred to the CMS Privacy Board.

CMS staff are trying to review and approve the Part D data requests in a timely manner, but we need to have requestors submit a complete and comprehensive package. This is a learning experience for all parties. The data requestor, CMS, RESDAC, CCW, obviously the more experience that everyone gains, the quicker the process will go.

My candid advice to everyone, is that it may be prudent for researchers to wait at least several months before submitting their data requests. They should wait until at least CMS produces more extensive guidelines and resource information that'll be available on our Web site.

At this point in time, I'd like to turn over the last speaker, who is (Barbara Frank), the Director of Assistance for RESDAC.

(Barbara Frank): It's a pleasure to have the opportunity to tell you more about the Research Data Assistance Center, RESDAC today. Many of you already have been in contact with our Help Desk possibly with Part A and B Help requests. But for those new researchers unfamiliar with RESDAC, the first stop should be our Web site.

As (Spike) mentioned it's resdac.umn.edu. It will be the portal to the most current information available about the Part D data. At this time, Part D information is currently located on our home page with links to the final regulation and Part D data elements list.

We currently have a link to submit your potential interest in the data and your research needs. Researchers will also be able to email suggestions about needs for a public use file, supplemental information, or statistics that (Dan Waldo) mentioned.

Some of what our Web site offers include information about available data, requesting data, CMS privacy policies, our hands on training workshops, outreach programs, frequently asked questions, technical publications, and data dictionaries, as well as links to the CMS Web site and the CCW Web site.

We will be updating our site as any new information is received from CMS. Once the data request documents have been finalized, we will be including a Part D under our requesting CMS data link. This Web page will supply information and documentation such as example letters, the Data Use Agreement, DUA, a data element justification guide, cost estimates, and all other information needed for submission of a CMS data request packet.

Again, all data request packets must be reviewed by RESDAC and the final original packet will be sent by RESDAC to CMS for their review and approval.

As information comes in, we will be updating the frequently asked question section and available data pages on our RESDAC Web site. In addition, RESDAC will also be presenting a number of Web casts to disseminate information about the Part D data and request process.

This will include data limitations, data element review, and the most up-to-date timeline for Part D data release. These will begin in August and may be as frequent as monthly Web casts.

In addition, we can be contacted with any questions via our toll free line, which is 888-9-RESDAC. We also have email at resdac@umn.edu or via or request response transmission system through our Web.

Thank you very much.

Natalie Highsmith: Okay (Rebecca) we're ready for our open Q&A portion. If you could just remind everyone on how to get into the queue to ask a question. Everyone please remember, when it is your turn, to restate your name, the state you are calling from, and what organization or provider you are representing today.

Operator: At this time, I would like to remind everyone, if you would like to ask a question, press star, then the number one on your telephone keypad.

We'll pause for just a moment to compile the Q&A Roster.

Your first question comes from the line of (John Carlson). You have the floor sir.

(John Carlson): Hi this is (John Carlson) from (Covance). And I have a couple of questions about the public use files that are being developed. I didn't hear a mention to the specific timeline associated with those. Is that also going to be like a five month approximately time line or is it going to be longer than that?

(Mark Smith): Well, it will be at least five months, because it's going to take us that long to load the data and get it all cleaned up. The specifications for the file have yet to be developed and so we anticipate that these files will be released on a rolling basis, as we get the specs put together, get the file cut, and then put it up for release.

(John Carlson): But it - do you think that it- that'll be - is there going to be a lag between when the identifiable data sets are released versus when the public use files will be released.

(Mark Smith): No.

(John Carlson): No. Okay. And will users be able to link the Part D public use file to the Part A and B limited data sets?

(Mark Smith): Hey it's hard to tell at this point, because we don't have the specs for the file. If we do put out a public use file with links to A, B, and D data, it's likely to be a freestanding file.

(John Carlson): Okay. And can I ask one more question? Do you know approximately when you're going to be accepting orders for the public use file?

(Mark Smith): The public use files that we don't have yet.

(John Carlson): Right.

(Mark Smith): Well, it'll be shortly after we get them put together. So, I would have to say, stay tuned, keep up on the Web site and we'll have more information posted for that.

(John Carlson): Okay. Thank you.

Operator: Your next question comes from the line of (Pat Devlin). You have the floor.

(Ed Bornicheck): Yes, hi. My name is (Ed Bordnicheck), Merck Research Labs in Pennsylvania.

Two related questions. I know you talked about the public use access database and you did present some overall guidelines for commercial institutions. So

I'd like to ask very specifically, will Medicare claims Part D data be made available to researchers from departments of medicine or epidemiology in the pharmaceutical industry?

(Spike Duzor): I'm a little confused. Can you be a little bit more specific?

(Ed Bornicheck): Well, just whether the - it would be possible to request the data directly if you are coming from within the pharmaceutical industry a department of epidemiology?

I'd want a little more clarification on who would have access to the Part D claims Medicare data?

(Spike Duzor): Let me repeat what I think your question is. Can Merck employees get request directly Part D identifiable data? Is that the question?

(Ed Bornicheck): Yes. That - or any company...

(Spike Duzor): Or any company. I'm not...

(Ed Bornicheck): Yeah, any company pharmaceutical researchers within that company.

(Spike Duzor): Right. We're following the same policy that we've had in effect for the last ten years releasing Part A and Part B identifiable data and we provide that information to organizations like drug manufacturers who fund independent universities. That way the manufacturer has a hand - they're not involved in the outcome, the research is free to be published, and it sort of meets the generalized definition of research and - that we've been following.

So that's what we plan to do, that as we've done for the last ten years, you would be partnering with a university.

(Ed Bornicheck): Thanks for the clarification. That seems like it would be answer from your - from the prior comment, but I just wanted to clarify that. It would have to come through an academic partner essentially is - and that is the way it has in the past.

The second question regardless of how the request came through, I want to know whether analyses of drug safety in Medicare claims Part D will allow access to medical charts to validate the diagnoses in the claims data? Will there be medical chart review available for full medical research use of the data?

(Penny Mohr): This is (Penny Moore). I just wanted to say that we don't have access to medical charts and so we cannot allow outsiders access to those medical charts. I guess that's it.

(Ed Bornicheck): Okay. So there wouldn't be accommodation for that, at least at this time.

(Penny Mohr): No.

(Ed Bornicheck): Thank you.

Operator: Your next question comes from the line of (Sean Hennessey). You have the floor.

(Sean Hennessey): This is (Sean Hennessey) of the University of Pennsylvania. I just would ask you to clarify what you mean by classes of drugs that are excluded for privacy reasons?

Can you hear me?

(Mark Smith): We're moving some microphones around here.

(Alissa Deboy): This is (Alissa Deboy) and I'm one of the authors of the rule. As we note in the preamble, there are certain records that are protected specifically -- it's under the provisions of 42 CFR Part 2, which are some public health regulations that protect the confidentiality of alcohol and drug abuse patient records.

And so, these requirements basically address the disclosure and use of alcohol and drug abuse patient records that are maintained in connection with the performance of any federally assisted alcohol and drug abuse program.

And so we're looking at insuring that any samples of claims that we use for nonpayment purposes excludes records that are associated with these treatment programs. Those are the records in particular that are protected.

(Sean Hennessey): Okay. Thank you very much.

Operator: Your next question comes from the line of (Connie Bishop). You have the floor ma'am.

(Connie Bishop): Thank you. I'm calling from Duke University Medical Center and the School of Nursing. We are a Health Informatics Research Group. We've a very specific question from one of our physicians as to where we would find what is called the physician signum, which includes the name of the drug, the root of the drug, the amount of the drug. And I have not been able to find that in

the data elements. I see 18 and 19 might cover it, but he's still looking for root.

So I was wondering if that is available in the data element?

(DanWaldo): This is (Dan Waldo). At present those - that information is not included among the elements.

(Connie Bishop): Okay.

(Dan Waldo): Well, at present, it's not among the 37 elements. That kind of information would have to be obtained through matching the 11 digit NDC with another data source and we're looking to - we're exploring ways that we might be able to do that, or at least that we can point to other data sources that people might be able to use to match that information on.

(Connie Bishop): Thank you (Dan).

Natalie Highsmith: Okay (Rebecca) next question please.

Operator: Your next question comes from the line of (Michael Ong). You have the floor sir.

(Michael Ong): This is (Michael Ong) from the UCLA. I was just again asking a question to clarify the privacy restrictions. And so I know that you just clarified that alcohol and drug abuse or the things that relate to alcohol and drug abuse may be restricted, I also was wondering about mental health medications, whether or not, there would be any restrictions on those?

(Elisa Deboy): No, not at this time. We are obviously restricting beneficiary identifiers where it's not specifically needed for a study, but not the claims for mental health drugs themselves.

(Michael Ong): Great. Thank you.

Operator: Your next question comes from the line of (Don Mews). You have the floor sir.

(Don Muse): (Don Mews) independent consultant. I'm curious about whether CMS is entertaining the notion of providing dual eligible data where the Medicaid data currently that the agency has is linked to the Part D claims and the Medicare claims?

(Spike Duzor): (Don) this is (Spike Doozer).

(Don Muse): Hi (Spike).

(Spike Duzor): We're hoping that our MAXS data for 2005 would be out by the end of the year and at that time we will probably consider putting the dual eligible information into CCW. We know that a number of researchers would like to look at the - for the dual eligible, the drug use patterns under Medicaid and how they may have changed under Medicare in 2006.

(Don Muse): Yes.

(Spike Duzor): So I hope that answers your question.

(Don Muse): It does.

Operator: Your next question comes from the line of (Steven Soumerai). You have the floor sir.

(Steven Soumerai): Yes, (Steven Soumerai) at Harvard Medical School. This is actually a nice follow-up to the previous question.

Let's say you're interested in the effect of the changes and benefit structure formularies preferred drug list going from Medicaid to the new Part D plan and someone is on, let's say diabetes or a schizophrenia drug and you're interested in the generosity of coverage in the new plan.

And perhaps a subsequent plan that they switched to. Is it still the case that one can, you know, match up the data from the individual to the plan level data to be able to look at the impact of benefit structure?

(DanWaldo): This is (Dan Waldo). The answer to that is a qualified yes. Depending upon the research design and the type of data that are being requested, in theory it's possible to map the plan generosity information onto the record onto the person so that we would - that you could do this kind of research.

The trick is to do that in a way that does not compromise the plans commercially sensitive data or the plan identity.

Woman: (Unintelligible).

(Steven Soumerai): I'm sorry. (Dee) was talking. We have a little conference call here going. So we can get the full data on the drugs and the formulary, though I see what you're saying (Dan), we discussed this at the meeting last fall. I think we were hoping for you know, knowing whether (Respirdol) is preferred for this

patient with schizophrenia moving to a plan and that would require a specific drug information.

(Dan Waldo): Yeah, that's - that moves us into dodgy - into dodgy territory and I think we'd have to look at a specific proposal in order to be able to respond.

(Steven Soumerai): Okay.

Operator: Your next question comes from the line of (Richard Sussman). You have the floor sir.

(Richard Sussman): Thank you. I'm (Richard Sussman) of the National Institute on Aging. We fund a considerable amount of research in Part D and I've had some questions coming from grantees, so in a sense I'm acting as on-boards-man for the research field.

One of the - several of the questions came in from (Dan McFadden) at University of California, Berkeley. Here's one, "Part D will encrypt a plan sponsor. Will the encryption allow researchers to determine whether the claimants expanded on various sorts of expended coverage? Each generic or full coverage in the gap, flexible or fixed capitation. Will it allow researchers to study switching between plan types or sponsors? Will it allow researchers to study the impact of availability and tier pricing of specific drugs and formularies on subsequent health outcomes and expenditures?"

That's the first set of questions. I have another set. But...

(Dan Waldo): This is (Dan Waldo). Yes, yes, and probably yes.

(Richard Sussman): Okay. That's good. Alright. Next question. "The data release does not include Part D plan specific bid data, rebates, risk sharing, reinsurance or payment information collected outside of a Part D claim. Does CMS collect data on specific drug prices in specific plans? Do stated drug prices net out drug specific rebates from pharmas to pharmacies? What about drug specific rebates from pharmas to pharmacies and/or sponsors? What does CMS do to assure that stated drug prices are what sponsors actually pay? What data will CMS release to provide researchers and the public the assurance that beneficiaries and tax payers are receiving the best market prices for drugs and are not being charged list prices that exceed the effective cost to sponsors when rebates are netted out?"

(Dan Waldo): To the first part of the question, the PDE record is intended to display the point of sale cost of the drug. So any off line transactions or -between pharmaceutical manufacturers and the pharmacy or the wholesaler and the pharmacy or the manufacturer and the plan are not reflected in these data and they're not covered by the regulation.

With respect to the question about whether consumers are getting the best value for the dollar or the best possible price, that's a qualitative question that is going to have to be determined by people who are using these data in research.

The question of whether the stated prices are what's actually being paid, is a program integrity issue that's being addressed outside of the PDE data release, but I know that they're - I know that CMS does have programs and procedures in effect to check on what's actually being paid and what's being advertised.

(Steven Sussman): (Dan) thanks. Is there a way in which a grantee or contractors could indeed get access to some of the elements that are not specifically included or are

specifically excluded, assuming that we could - that there would be some way to protect privacy of the commercial interests privacy in terms of what gets released in any publication, for example?

(Dan Waldo): I'm going to ask (Alissa) to address that.

(Alissa Deboy): The answer is, the only way that a contractor would be able to obtain that type of information is for payment purposes only. A contractor that we contract for payment purposes, those elements are not the subject of this rule.

(Steven Sussman): Does the...

(Alissa Deboy): They've never contemplated.

(Steven Sussman): Would the Secretary of HHS have the ability to permit such data to be analyzed?

(Abby Block): The answer to the question is no. It's beyond the scope...this is (Abby Block). It's beyond the scope of the rule. We've been very specific in terms of what the rule covers and what it doesn't cover and those limitations are in effect and there are no workarounds to those limitations.

(Steven Sussman): Okay. Thank you.

Operator: Your next question comes from the line of Dr. (Carol Mangione). You have the floor ma'am.

(Carol Mangione): Hello. This is (Carol Mangione) from UCLA. I just had a question. I heard you say that although there won't be plan identifiers, that there is a plan to

have to supplemental files that describe benefit design and could be linked to the individual subscriber level.

I wondered what the time line was for creating files with regard to benefit design?

(Dan Waldo): This is (Dan Waldo). We're working on those specifications now and I would anticipate that those supplemental files will be available about the same time that the regulatory - that the PDE data themselves are available for release.

The difficulty that we face is, trying to figure out what, you know, how to construct these supplemental - this supplemental information and how to make sure that the combination of the supplemental information and the PDE elements themselves that are released don't compromise either beneficiaries' privacy or plan commercial sensitive information.

But, I would hope that we would be able to get these out fairly promptly, because they're going - it would seem to be that they'd be an integral part of any research that's done with the data.

(Carol Mangione): Thank you.

Operator: Your next question comes from the line of (Julia Meerling). You have the floor ma'am.

(Oli Deventechon): Hi. Actually this is (Oli Deventechon). I work with (Julia Meerling) and the Pennsylvania Children's Hospital.

We have a question concerning the completeness of coverage in Part D. If we have beneficiaries eligible for Part A and B, how many of them, what proportion of them can we expect to have covered by Part B?

And additionally, if - when they're covered, what drugs can we expect to see in Part D? If the drugs are not covered by Part D data, then is their release of drugs not covered by Part D?

(Nancy De Lew): Hi, this is (Nancy De Lew). We have on our Web site a Press Release we issued at the end of January and it reviews the enrollment information for Medicare beneficiaries. The highlights of that here, we have in 2008, we have about 44 million Medicare beneficiaries who are eligible to enroll in a Part D plan, that is they have either Medicare Part A or B coverage.

Of those individuals, we have a slightly more then 25 million enrolled in a Part D plan. As (Dan) - that's a little bit more then half of the eligible Medicare folks are enrolled in a Part D plan. As (Dan) noted though, some of those individuals in a Part D plan also have drug insurance coverage from another payer.

An example of that is the VA. What we will have in our database, are their Part D claims. We do not have any claims for drugs that they may have had reimbursed from another source of coverage, such as the VA.

So what we want to make sure people understand is, we have considerable information about the Part D enrollees, but we may not have their entire drug history.

(Dan Waldo): Right. And this is (Dan Waldo). It's generally speaking the drugs that are - that would be included in the Part D file would depend upon the formulary of

the plan in which the enrollee has signed up. Generally speaking there are broad classes of drugs that are not covered by Part D and the basis - by the basic plans, Benzodiazepines, Barbiturates, fertility drugs, and things like that, but, plans that have the option of offering those as part of an enhanced benefit.

So the answer to your question about what drugs would not be covered is difficult to answer in the absence of information about what plan they're actually enrolled in.

(Oli Deventechon): Okay. Okay, thank you.

Operator: Your next question comes from the line of (John Carlson). You have the floor sir.

(John Carlson): Hi, I have another question about the public use file. I understand that those haven't been developed yet, but I saw that on the CMS Web page the - there's kind of a standard set of policies and ordering instructions that apply to those files.

Are those policies and the Data Use Agreements and things like that likely to be the same for the Part D public use file or will there be specific policies and agreements related to that file?

(Spike Duzor): This is (Spike Doozer). I think you're referring to the policies on our Web site for our limited data sets.

(John Carlson): Right.

(Spike Duzor): Okay. We're actually thinking about a limited data set requires some justification requires a Data Use Agreement and it does contain some level of

patient identifiers. We're actually considering for Part D to create a true public use file that the public would not be able to - it would contain no facial identifiers and that you would not able to identify an individual.

Under that case, we may not even require a Data Use Agreement. I'm hesitating on that. We would like to - when we create the data, when we create the public use files, we would like to monitor who is using the data and why, because it would help us develop public use file version two, version three.

But I think that the process of - as we're thinking right now, would be simpler then the limited data sets.

(John Carlson): And in the Q&A document that was posted in conjunction with the final rule, I think the - it had said that there would be a limited data set. It sounds like maybe now that's not definite?

(Spike Duzor): We - we're looking at producing multiple data sets. We think that the broadest usage is probably a public use file, then commercial entities could use it, a broad base of organizations could have access to it that normally wouldn't have access to something like a limited data set.

(John Carlson): But it seems like that - and I apologize I don't want to take up too much time, but it seems like the - if it's a public use file rather then a limited data set, that would potentially compromise the ability to link to the Part A and Part B benefits. Is that accurate, or is that not necessarily true?

(Mark Smith): I think that's accurate. But, that does not preclude the possibility of putting out a public use file that has A and B data already linked. Okay. So, in general, a public - you can pretty much bank that a public use file is not going to be linkable to anything that you already have.

But if we can produce - if we can think of a way to produce a public use file, let's say for example, just as a hypothetical example, let's say we took 75,000 Medicare enrollees samples nationwide. No geographic identifier, but we could take the A, the B, the D data, beneficiary characteristics, plan characteristics, link them together and put it out. Okay.

That kind of a thing where the data are already linked is quite possible.

(John Carlson): Okay. But just to confirm. It sounds like the limited data set hasn't been completely ruled out, but you're not completely sure, whether or not, that's going to happen, is that right?

(Spike Duzor): I think - this is (Spike Duzor) again. I think it would be very helpful if you have specific ideas or you have some ideas on how to create a limited data set, if you could send them to us. You're right, we haven't ruled out anything and we really are looking for public input.

(John Carlson): Okay. Thank you.

Operator: Your next question comes from the line of (Carolyn Gray). You have the floor ma'am.

(Kimberly Fox): (Kimberly Fox) from the University of Southern Maine. I just wanted to ask, in terms of the supplemental plan information that you're considering potentially including or adding to the database, does that include information on medication therapy management plans by the plans that are or and more generally, if you're seeking input from those of us in the research community, do you have a list of the types of information from the plans that could be potentially available so that we can weigh in on what would be beneficial?

(Dan Waldo): This is (Dan Waldo). At present, the - we know from the information that's been submitted to CMS the three basic types of utilization management, quantity limits, prior authorization, and step therapy.

Whether the plan itself has another, you know, a management system outside of that...

(Penny Mohr): I can answer.

(Dan Waldo): Can you. Okay. Here's (Penny).

(Penny Mohr): I do know that for the first comment here that we are requiring plans to submit at an individual level, whether or not, a beneficiary a participant in a medication therapy management program. Well, we're going to see as to, whether or not, that would be something that would be feasible.

(Dan Waldo): But it's not available for '06 and '07?

(Penny Mohr): It's not available, yeah.

(Dan Waldo): Yeah, it's not available.

(Kimberly Fox): And that's at the beneficiary level. I understand, so you're saying that in the future it may be, whether they're in a medication therapy management program, but I also understand the plans are required to submit medication therapy management plans and whether there was any way that you had categorized them or in some ways collected information that would then be available at the plan level?

(Alissa Deboy): Those were required for our programs and our operational purposes, we have not explored in any way, we have not decided whether or not, we're going to be able to provide any information on them.

(Kimberly Fox): I'm not sure I heard that - you're a little far from the phone. I'm sorry.

(Alissa Deboy): We have not, while plans are required to report that information to us for our oversight purposes, we have not explored, whether or not, we would provide any information on the supplemental files with respect to medication therapy management.

I would just suggest that you, you know, include comments to RESDAC for us to consider.

(Kimberly Fox): Okay. We'll do that. Thanks.

Operator: Your next question comes from the line of (Shawkee Lou). You have the floor.

(Shawkee Lou): Hello. This is (Shawkee Lou) from UIC. I'm wondering like with Medicare Part D data, first following the previous question, that beyond the tool potential privy Part D data? Like a - do we need such a research as the impact of Medicare Part D on medication switching and clinical outcome if we - is it possible to do this kind of research on that?

(Dan Waldo): This is (Dan Waldo). There were some problems with the phone. Let me see if I can - let me paraphrase your question. Is I understand that you were asking whether it's possible with the data that we have to do research on the effect of Part D on clinical outcomes?

(Shawkee Lou): The first thing is medication switching and then the clinical outcome.

(Dan Waldo): Medication switching and clinical outcomes.

(Shawkee Lou): Yes.

(Dan Waldo): Yeah, I mean. (Penny) and are going yeah. Yeah, that's possible. Yeah. Now the difficulty that we would have with something like that, is in an earlier call, in response to an earlier call, we pointed out that we don't have any chart information. So clinical outcomes would be limited to those clinical outcomes that you could detect from say, (ICD-9) or procedure codes on Part A and Part B claims.

(Shawkee Lou): Yeah, so for the - for this kind of situation, they can use the (ICD) code to identify each patient and to follow them through the pre and the post Part D. Am I correct?

(Penny Mohr): We would have an encrypted patient identifier that would allow you to follow a patient in a longitudinel way.

(Shawkee Lou): Okay. And also, for a further continued - could we get the information like for pre (unintelligible) data with the dual eligible decisions?

(Dan Waldo): I think (Spike) mentioned earlier that our hope is to be able to load the 2005 Medicaid analytic extract data into the CCW in probably - in what about a year?

(Spike Duzor): Yeah.

(Dan Waldo): In about a year, at which point, the Medicaid data can be linked to the Part D data.

(Shawkee Lou): Okay. (Unintelligible), for example a user encrypted code?

(Dan Waldo): That is correct.

(Shawkee Lou): Okay. Thank you.

Operator: Your next question comes from the line of (Susan Richardson). You have the floor ma'am.

(Steve Paris): Hi. Good afternoon. Actually, this is (Steve Paris) from the New York State Office for Mental Retardation.

You brought up that you are looking to have the 2006 Part D data available on line somewhere around - on or around December 1st of this year. Do you have a timeline or timeframe for bringing let's say '07 data on or '08 data and then once you do get "current" what kind of currency do you envision? Will stuff be available within the next quarter, month? Do you have any kind of ideas of where - how we're going to move towards a state of currency in this?

(Spike Duzor): This is (Spike Duzor) and other people can jump in. We're probably not going to start loading '07 data until we're - have done some initial quality checks on '06 and make sure that it's - that everything seems to be working.

I would think that early sometime in '09 then we would be loading '07. We're not exactly sure about the frequency of data, but why don't you assume for the first couple of years, that the data would be based on an annual basis and then

we'll kind of reinvestigate the need for - or our ability to produce more timely data.

(Dan Waldo): This is (Dan Waldo). I just wanted to add that it's important to remember that the method by which we receive Part D data is not the same as the method by which we receive A and B data. A and B data come in within a certain time of the time of service, but the Part D data are submitted to us by the plans. And so there's a - there's not necessarily a specified time within which that happens.

So, in theory we could get it all in one lump plop in July for the previous calendar year.

(Steve Paris): So that means that the notion of a current basis has somewhat vaguer delimitation in Part D data then it does in A and B?

Woman: This is (unintelligible). Just to clarify that a little bit. The 2007 for example, the data wouldn't be substantially complete until later this summer, when the PDE are required to be submitted for you know, payment reconciliation purposes.

So...

(Steve Paris): Okay, we've got one last question here to (Omar) and that is that, here we serve about 65,000 Part D recipients through the state programs and our voluntary agencies many of whom we are the legal guardian for.

As opposed to a broad sweeping research initiative, we would really be interested in data that pertains to our specific population. You mentioned the use of the ability of step finder files. Do you believe that you would be able to

accommodate our specific needs in so much that we may be able to present a finder file of say, the (HICNs) or our 65,000 dual eligible Part D recipients in order to get a really - a very specialized results file?

(Nancy De Lew): Hi, this (Nancy De Lew). What (Dan) was talking about and (Spike) were for the general research community in terms of when we anticipate making the 2006 and 2007 data available. We know that there are requests from state agencies to try to get data on a more timely basis. We're going to have some specific conversations with states. We would invite you to be a party to those.

I know we're going to be speaking with the National Association of State Medicaid directors. Some of those individuals tomorrow. So we would invite states on this call to, you know, have another state conversation with us about availability.

(Steve Paris): Thank you.

(Nancy De Lew): Yeah.

Natalie Highsmith: Okay (Rebecca) we are getting close to our 5:00 hour in on the east coast. I'll turn the call over to (Alissa Deboy) for closing remarks.

(Alissa Deboy): Thank you again. This is (Alissa Deboy) from the Center for Drug and Health Plan Choice and again I'm one of the authors of the rule. I'm sorry we do not have time for all of the callers, but I hope that all of you here and those listening found this session informative.

As you have heard here today, we are in still some ways at the very beginning. We are hoping to have a database CCW ready that stores and links the Part D

data in a manner that protects sensitive information without hampering important research projects.

We ask for your patience as we prepare that database in the next few months and need your input as we design public use files and add plan characteristics to the PDE data.

In closing I want to say thanks to all of you who commented on the rule back in October 2006. This was a joint effort and it took a while, but it was not because of lack of support for this rule. No group of government agencies alone could fund or conduct the number of studies that will be made using this data, by many people that participated on this call today.

So we thank you for all of your work to come. We recognize that there's a lot of information to absorb on this call and as (Spike) and RESDAC mentioned, there will be additional training sessions beginning in August. We're still working out the details, but please look to RESDAC's Web site for more information.

That Web address is at the bottom of the agenda for Open Door Forum. And just a reminder, this session in its entirety will be available in the CMS Open Door Forum Web site approximately June 18th.

But finally, unanswered questions may be submitted by email to the ptddata@cms.hhs.gov which was included on the Open Door Forum announcement. We'll use those questions to develop future frequently asked question documents and to prepare our guide to requesting Part D data.

So thank you very much and have a good night.

(Rebecca) can you tell us how many people joined us on the phone?

Operator: Six hundred and seventy six ma'am.

(Alissa Deboy): Six seventy six. Wonderful, thank you.

Operator: This concludes today's conference call. You may now disconnect.

END