

# FALL 2012 CMS CONFERENCE



## TRANSCRIPT

### Day 1 07a: CDAG ODAG Findings for 2011 Audits

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Good afternoon. I'm Jennifer Smith. I'm the Director of the Division of Appeals Policy at CMS. And I will be going through the first part of the presentation, and then I'll hand it over to Dr. Kelman to discuss clinical decision making, which I want to give plenty of time to because I think that's probably the most important part of our presentation.

Okay, so what are we going to do today? I'm sure earlier today when you were in the Program Audit Session, you heard Tawanda and Jonathan go over some of the things that CMS views as immediate needs or immediate corrective actions. And I'm sure you noticed that there was a lot of coverage determinations, organization determinations, appeals, and grievance items on that list. Why? Why does CMS think that's so important? Obviously, your primary purpose is to administer your benefit, your formulary. And usually, things go through, things get paid, people get services, and there's no problem. And appeals is a small portion of what you do.

However, it's your failsafe because obviously when claims are processing, they can go wrong. When people are making organization determinations or appeals, that's a manual process. And this is your failsafe, your chance to – if things didn't go correctly the first time around – correct it, catch it. And if you don't, then it could mean that an enrollee is going to go without a needed item or service or medication. And so obviously, CMS is going to view that very seriously.

We have had, I guess, two years now of Part D audits – the “new audits” as I like to call them. And this first year for Part C, I can say unequivocally that it's been incredibly educational. I think not just for the Plans who've been the subject of the audit, but certainly for CMS and the policymakers and Central Office as we have been able to see common areas where Plans are either not fully meeting our expectations, potentially not understanding what our performance expectations are, or where our policies need to be strengthened, clarified, expanded upon, etc.

So I think what Dr. Kelman and I would like to do is just highlight some of those common areas for you today and spell out our performance expectations, and then hopefully leave some time for any questions you may have. So you're not going to see me really reading from my slides. I assume you all can read them yourselves. I'd prefer to just talk to you about what we've been finding.

So Part D first – what are we going to cover in Part D? Effectuation, processing of Exception Requests and Grievances, and as I mentioned before, Dr. Kelman will do clinical decision making after the fact. So what are we talking about when we're talking about effectuation? This is the definition from Chapter 18 in the Manual; but it's basically payment of a claim, entering an authorization into the system to allow an enrollee to get a prescription at point of sale, or entering

an authorization into a system when you've received a reversal of your adverse decision from an appeal adjudicator.

So the common deficiencies in effectuations – so timely effectuation of approval in the system was a common one. So many of you take your requests over the phone from enrollees or prescribers. And we saw over and over again where the Plan would issue a favorable decision, but then fail to go into the system and actually enter the authorization. So an enrollee would go back to the pharmacy, not be able to get their prescription, have to call again, maybe even get a second request and still no authorization in the system. Sometimes this was just a couple of days lag, sometimes there were months. So I would definitely say – I'm sure you also heard if you were in the Compliance Session, Marianne probably talked a lot about internal controls and ensuring that you have mechanisms in place to recognize these things and rectify them quickly. Normally, you would hope that a Plan would catch this when a second request came around, or even before then, to make sure that there are standard operating procedures for entering those authorizations into the system.

Another big one was what we're calling accurate or appropriate effectuation. This mainly had to do with Exception Requests. So if you received a formulary exception or tiering exception request from one of your enrollees and it's granted, we require that that exception be good through the end of the Plan year. We saw authorizations that were for 24 hours, 7 days, 30 days, 18 months. We're not so concerned about the 18-month one; that's more generous than what we ask you to do. But to the extent that you've granted an Exception Request, it has to be entered into the system properly through the end of the Plan year.

And then timely notification to the beneficiary – since prescribers and physicians are a lot of the people who are calling and requesting coverage determinations and appeals, we saw oftentimes a common problem was the Plan would follow up with the prescriber and the physician, but they would never make any notification to the beneficiary -- or if they did so, they did so untimely. So that was a big problem. We also saw a little bit of Plans not timely effectuating or entering authorizations as a result of favorable IRE or ALJ decisions – IRE being the independent review entity and the Administrative Law Judge decisions.

I know that there is a monthly report that both the Part C and the Part D IRE issue, which is that Compliance Effectuation Report, which goes to Plan account managers. One thing that I would remind you all of is when you have effectuated a decision to make sure you're filling out that Compliance Effectuation Form and sending it back to MAXIMUS. Otherwise, they'll have no way of knowing that you've actually effectuated the decision. And we'd hate to have you on a report somewhere saying that you've been naughty when you've actually been complying with our requirements.

So timelines for effectuation – and these are for not just your decision making, but also your effectuation. Coverage determination – 72 hours for a standard request, 24 hours for expedited; redetermination, 7 days, 72 hours; IRE decision, 72 hours for standard or 24 hours for expedited from your receipt of the decision. Requests for Payment are 14 days; and just note that they're all calendar days, not business days.

Another big one that we saw was rules for supporting statements. You can toll your decision making time frame. Or your decision making time frame doesn't even start on an Exception Request until you receive a supporting statement from the physician or prescriber. That only applies to Exception Requests – not to all coverage determinations and appeals. We saw some Plans that were tolling their time frame or holding their time frame, thinking they could do that on all requests. So it's specific to exceptions.

Another thing too is as well, your decision-making time frame doesn't start until you get that supporting statement. We do have an expectation that you would reach out to the prescriber or physician and be clear in what you need from them in order to process the request. We've seen a lot of different things. I know Dr. Kelman will probably get into this a little bit more with denials – but just making sure that you're clear in what you need, you're conducting your outreach, and you also are sure that you don't already have the information on hand. We did see some of that as well, where people were tolling things for a supporting statement when they really had what they needed in their case file already.

So Part D Grievances – that's the definition of a grievance from Chapter 18. But basically this is a complaint you receive from one of our enrollees generally about your benefit structure or your operations processes, could be about quality of care, could be related to copayment levels.

Common Deficiencies – we're continuing to see a lot of Plans who are misclassifying Requests for Coverage as grievances. That's a problem for two reasons. One, obviously there is a very rich appeals process in Medicare – both on the C and D side. And if you put someone in the grievance bucket as opposed to the coverage determination or organization determination bucket, they're not getting the benefit of that appeals process. Secondly, the decision-making time frames for grievances are much longer. So if you have an enrollee that's waiting for a drug and they've mistakenly been put in the grievance bucket, they are having to wait and go without potentially needed medication for much longer than CMS would intend.

So misclassification – I would say that you really have to ensure your CSRs or whoever you have at your organization processing or intaking these complaints that they are well aware that if the enrollee is in any way requesting coverage of a specific drug, if they are complaining about their copay that they paid on a specific drug, that those are coverage determination requests and that they need to be vetted through that process. You may have someone calling in and part of their complaint could be a request for coverage and part of their complaint could be a grievance. And you're going to have to process it through both avenues. But I would also suggest that if you have CSRs that don't have access potentially to, say, like your claims processing system or any kind of history on your enrollees, you might want to give them that access because it is helpful if an enrollee is calling in and saying, "I couldn't get this drug," to be able to look at their claims history and see whether or not they're on that medication because that's going to be a clue that they're requesting coverage.

Proper Resolution – we continue to see issues here. I mentioned this I think at last year's Fall Conference. But unfortunately we've seen it in some Plans – like the resolution will be, "The enrollee got frustrated and hung up." No, that's really not the resolution. That's just the enrollee

getting frustrated and hanging up. We would expect you to follow up with them, to write them a letter, to address whatever issue they raised in the phone call.

Another common one, more common than the previous example, is that an enrollee would raise maybe three issues and the response addressed one. You kind of really need to QA those letters, make sure that all of the enrollee's concerns are addressed in the letter.

And then finally, Timeliness and Notification – so there were cases where people did not respond, so they were just open, and other cases where they were just well beyond the time frame.

So I think we already covered this. You've got to determine whether it's a grievance, a coverage determination, or both. They have to be resolved appropriately. It can be filed orally or in writing. You have to notify the beneficiary of the resolution within 30 days. And if the grievance is about a refusal to expedite a coverage decision, you have to respond within 24 hours.

And I think we already hit all of that, so we can skip that part.

Okay, Part C – this is going to sound very familiar because it's a lot of the same issues. So in Part C the primary things that we noticed where there were common patterns of deficiencies again were around effectuations, appointment of rep forms, and Part C grievances.

So effectuation – what are we talking about with effectuation for Part C? Again, we're talking about pre-service requests for coverage and entering that authorization in your system to let the future claim that comes in after you've done the prior authorization to pay.

Processing and Paying Claims from Non-Contract Providers – we're not talking about contract provider claims. And I wanted to take this opportunity to remind everyone that to the extent that a contract provider provides a service to your enrollee, our expectation is that that was a favorable decision. They've gotten that service. They cannot be held liable. And if the enrollee can't be held liable, then there is no Subpart M appeals process. So your contracted provider should really never be in our Medicare appeals process. If you've set up your own internal appeals process for your network providers, that's fine; but they shouldn't be in our process.

So Common Deficiencies – again, timeliness of entering the authorization into the system if you've done a Prior Authorization Request.

Timeliness of Notification to the Beneficiary – again, we saw where if the physician or prescriber was making the request, the Plan called the physician back and never sent anything to the beneficiary. And a big one was an inappropriate extension of the deadline or inappropriate understanding of the time frame to make a decision. So we saw some people using the grievance time frame. We saw others who used the – in Part C, there is a 14-day extension; however, it's to be used rarely and should be in the best interest of the enrollee. We saw numerous Plans where every single decision they made, there was a 14-day extension invoked. We shouldn't see that.

Same thing here – in Part C you have to both effectuate and notify the beneficiary within the decision-making time frame. And here are the time frames. So for organization determinations,

you have 72 hours if it's expedited; 14 days for a pre-service request; and 60 days for payment. For Plan level reconsideration, 72 hours for expedited, 30 days pre-service; and 60 days for payment. For IRE reconsideration, 72 hours for expedited; authorized within 72 hours or provide no later than 14 days for a pre-service, 30 days for a payment, and that's the 14-day extension that we were talking about – and again, calendar days not business days.

Appointment of Rep Forms – we saw a pattern of Plans dismissing requests or invoking extensions attempting to get Appointment of Rep Forms from physicians when they were requesting a pre-service organization determination or requesting a pre-service appeal on behalf of an enrollee. That is not a requirement. A physician, if they are treating an enrollee, can initiate one of those requests on their behalf. So there's no need to obtain an Appointment of Rep Form.

Part C Grievances – again, that's the definition from Chapter 13 of the Medicare Manual. And same thing -- this could be a quality of care complaint; it could be a dissatisfaction with your network, dissatisfaction with your operation, etc.

Common Deficiencies – again, very similar to Part D. Misclassification of a grievance as opposed to an organization determination or appeal – so not understanding that they were actually calling in to request coverage of an item or service.

Untimely Resolution or Late Notification to the Enrollee of the Resolution – we again saw letters here where they might be three or four issues raised in the incoming, but only one issue discussed in the letter back. And then unfortunately a mishandling of quality of care complaints – if you're enrollee brings a quality of care complaint to you, they have a right to file a complaint with the QIO. So you need to give them, in your response, the information that they need about filing that Quality of Care Complaint with the QIO.

So just some basic requirements for Part C grievances – you have to respond within 30 days, 24 hours for an expedited grievance. For quality of care grievances, again, you have to respond in writing and include the enrollee's right to file with QIO.

And this is really for C & D – the procedures for tracking and maintaining records – it's kind of like you probably say to your providers, "If it's not documented, it's not done." It's the same thing with us when we come to audit. In order to be able to track your responses, understand whether or not you're complying, you have to have adequate systems in place to know when you received a request, when you responded, that you can capture any of the communications you had – especially if they were over the phone as well as in writing – so that you can not only have that for your own internal controls, but have that for CMS.

And then just a note that you must accept oral or written grievances. With that, I'm going to put the question button up. But I'm going to turn it over to Dr. Kelman, who's going to talk about the patterns he saw with clinical decision making.

Thank you, Jen.

Thanks, everybody, for the interest you're showing in the CDAG and ODAG portion of the conference. Now that Jen has explained the program completely, I'm going to explain and focus on the clinical decision making part of the audit process. The goal of this presentation for both of us – and I'm told you're supposed to have goals nowadays – is to make sure that all future CDAG and ODAG processes for our plan are perfect and that we never have a negative finding on audit again. This will by the way certainly guarantee better access for our beneficiaries going forward.

We always, as a rule, believe in communication, education, and preemption of problems rather than regulatory findings. Since the audit process is a clinical process, I'm going to try to walk through as many variations of the clinical processes as possible – starting with CDAG, the Part D clinical processes, and going to ODAG as time permits.

As we've said before – and it's very important to make sure everybody understands this at the beginning – we view our Plans as more than indemnity insurers with networks. We view them as sensitive to and responsible for coordination of care, which is not only central to coverage determinations, organizational determinations, but central to quality as a whole. It's at the basis – at the center – of the Triple AAA in better health, better care, and lower costs.

Let's start with the CDAG audit. The first effort is to establish responsibility division between the Plan and the PBM. Who organizes the P&T Committee integration of the initial formulary? Who actually does adjudication of the claims – which is almost always the PBM, but not absolutely always? Who actually receives the initial coverage determination? Who does the deliberative process? Who does the outreach? Who issues the decision? Who does the redetermination requests? Who does the deliberative process for the redetermination requests? Who issues the decisions? And if necessary, who refers to the IRE?

No matter what the division of labor, the activities of the PBM are responsibilities of the Plan. If we get nothing else out of this presentation, I'd like to be certain that I never again hear a Plan tell me that, "It's not our fault; it's the PBM's fault." PBMs' faults are Plan faults.

The second step is to define the date of the negative adjudication if there is one, the date of the first receipt of coverage determination, and the date of beneficiary enrollment. These three will in general determine the transition status of the case we're looking at. Then, and usually most important, we look at the reason for the initial non-adjudication. Most commonly, it's because of an off-formulary drug. Now when I say, "off formulary," it means it's also off formulary not only in the Plan website, but in the HPMS submitted and approved formulary to CMS. That last point will be true for every point we're going to make in this presentation.

Or, second possibility, it's on formulary with prior authorization, which are generally based on the label. Next, it can be on formulary with a safety quantity limit which is based on the FDA label. Or it can be due to a quantity limit that required approval beyond the label. It can be a B versus D non-adjudication. In certain ways, these are the most complicated because they're indication-specific and often site-specific. For example – and I'm going to get in the weeds in this because you are our Plans after all, and these are decisions you're going to have to make. A DME pump drug or a nebulizer drug is Part B in the home, but it's Part D most often in the nursing home. An immunosuppressive drug like cyclosporine is Part B for transplants in most cases, Part D for

vasculitis. Hospice drugs during hospice are not Part D drugs. ESRD bundle drugs, such as ESAs, are not Part D drugs in that setting. NUSA drugs – not usually self-administered drugs – can be B or D, depending on the access site of the drug. A drug can be on formulary with step therapy.

By the way, the clinical rationale – the step therapy – must conform to statute, which is to stay the first step has to be for medically-accepted indication to get to the second step. As an example, a Plan couldn't require pancreatic lipase as a first step to excess simvastatin to treat hyperlipidemia since pancreatic lipase is not MAI for hyperlipidemia.

By the way, every example I use will be something that has appeared in one or more of the audits that we do.

The transition – first 90 days – best practice is that a transition letter be sent and that the beneficiary be worked through so there's never a need for a negative adjudication. The pre-service request for a coverage determination is absolutely okay in Part D and saves everybody a lot of problems. It's also a very efficient way to do this process.

Then, when was the incoming request for a coverage determination for a non-adjudicated drug? It has to be determined to be urgent versus non-urgent for a timeliness assessment. And I underlined this in notes; and if I had slides, I'd underline it. The information submitted must be adequate for determination of the exception request or outreach for needed information is required. I can't repeat this enough, and it's just as true for organizational determinations as coverage determinations.

DUM-specific information must be accessed either in a Plan-specific form or a structured call, and outlines the clinical information needed to meet the DUM criteria. Tolling for gathering adequate information for an Exception Request is permitted and, in fact, encouraged because a decision without information in certain ways is worse than no information at all. We aren't looking for rush to a flawed decision based on inadequate information.

The Deliberative Process – This is often the hardest part because adequate information is needed. All formulary exceptions – by definitions it means that the on formulary alternatives are not appropriate for the individual beneficiary who is requesting an off-formulary drug – which means it didn't work, it failed, or there's a contraindication or analogy. And again, it has to be used for medically appropriate indications. For example atorvastatin, which is Lipitor, may be needed for somebody who has failed all three of the on formulary statins that are in the Plan's formulary.

Adequate information for fulfilling drug utilization management, PA and step -- again, it has to be based on the Plan requirements and it has to be based on the outreach information gathered; required diagnoses; place in therapy – first line or second line; safety – for example, a skin test before a tumor necrotic factor blocker for rheumatoid arthritis or an age edit for high-risk drugs in the elderly – the so called Beers list. As a note by the way, Beers list drugs are never absolutely contraindications. They're relative contraindications which can be overcome by a physician's statement as to balance of benefit and risks.

Sometimes adequate information for formulary exceptions will be available in old claims, which makes it much simpler. For example, a claims history of someone who failed simvastatin, pravastatin and lovastatin may be considered if documented and should suffice for off-formulary exceptions for atorvastatin.

Outreach – key to a coverage determination process and to the OD as well – and again, incomplete data is never a reason for a negative determination. If the adequate information isn't available in the submitted Coverage Determination Request, the provider must be contacted before denial. In other words, if the Coverage Determination Request notes that the specific first-step drugs are tried and failed, it's adequate information. If no information about a first-step drug is given, it's not adequate information.

In a PDP – and we realize that PDPs don't have network doctors – a good faith effort must at least be made. And this, by the way, doesn't include a fax on a weekend at five o'clock. For an MPAD for in-network provider, the contact with the provider is required. There are no exceptions. Physician non-compliance is never a reason for denial. Remember, in the end, the Plan Medical Director is ultimately responsible for information to determine the appropriateness of a coverage determination – and this is equally true for organizational determinations.

Sometimes by the way, the PA Form is overly burdensome. I saw one with 82 questions, and sometimes you get PA fatigue. A positive coverage determination is generally, as Jen said, for the remainder of the Plan year with some rare exceptions, such as in a course of antibiotics or certain narcotics.

The Negative Determination Letter is very important, which is why the division of labor has to be defined between the Plan and the PBM. It has to be specific to the drug as requested, which must be restated; the denial reason has to be in plain language; and it has to have enough information for an appeal. For example – and by the way, these are just examples, if there's any pharma company whose drug I mentioned is here, it's not personal – or formulary without the trial of a formulary alternative. It's important to list the formulary alternatives and the generic alternatives to brand if relevant.

For example, Lipitor 20mg tablets – and I'm going to actually read this – “We are unable to agree to your request for an off-formulary exception for Lipitor 20mg tablets because based on information provided, you have not tried the formulary alternatives available nor are you allergic to the formulary alternatives available. Simvastatin, lovastatin, and atorvastatin are drugs in the same class as Lipitor and covered at a generic copay of \$20. Atorvastatin is, in fact, the generic version of your requested drug. Please discuss these alternatives with your doctor if you wish to appeal...etc.”

B versus D – Now, this gets complicated because for the Part D Plans, a denial for B versus D requires a description of the referral to B billing. For an MA Plan, they're also the pre-service billing and so they have to make an accommodation for a provision. A Part C Plan cannot just deny a drug for B versus D and leave the beneficiary on their own. For example, cyclosporine 25mg capsules – for a PDP, the letter might go, “We are unable to agree to your request for cyclosporine Gengraf capsules because this drug is covered under your Part B benefit as treatment to prevent transplant rejection. Please ask your pharmacist to submit the claim to Part B Medicare for coverage. If you

wish to appeal this decision based on a different use of cyclosporine, such as psoriasis or rheumatoid arthritis, or any other reason you feel is relevant, please see information on appeal rights below.”

For the MAPD Plan, it would be different: “Please direct your pharmacist to call the following number at your Plan to arrange health plan coverage for cyclosporine. If you wish to appeal...etc.” PA Fulfillment – critical, absolutely critical to list the required elements of PA that have not been fulfilled. For example, Humira 20mg injection: “We are unable to agree to your request for Humira adalimumab injection because based on information you and your physician provided, you do not meet clinical criteria for this drug. Because of the risk of TB, a negative TB test is recommended for the start of this therapy. Please discuss this recommendation with your doctor. If you wish to submit information related to this requirement or wish to appeal the requirement, please see information on appeal rights.”

Step Therapy – list the specific first-line drug on formulary – Tarca 1240 – “We are unable to agree to your request for Tarca 1240 because according to information received from you and your doctor, this is your first drug for hypertension, but it’s not considered a first-line drug. Multiple other drugs for hypertension are on the formulary as first-line treatment including Amlodipine and Diltiazem, as well as Captopril and Lisinopril. Please discuss with your doctor for alternate therapy. If you wish to appeal this decision...etc.”

Quantity Limits – list the maximum allowed. By the way, if a dosing simplification issue is the reason for denial, describe the appropriate dose available. This type of non-adjudication by the way can often be taken care of at point of sale. Lipitor 20mg, requested 60 for 30: “We are unable to agree to your request for 60 tablets of Lipitor 20mg as a one-month supply as it exceeds our quantity limit. However, 30 tabs Lipitor, 40mg can be supplied. Please discuss this alternative with your doctor. If you wish to appeal the decision...etc.”

The standard appeals line which needs to be included, it needs to be timely, and the information for the Denial Letter needs to be adequate to request an appeal.

The Redetermination – The incoming request has to be received and dated. The outreach, again, is critical for informed decision. If original information is inadequate -- new information, new physician contact, and a new review. Cannot treat Redetermination Request as a reopening of the original decision unless a Plan error is in the original denial.

Negative Redetermination Request – must be specific to drug; a plain language explaining the denial; and the reason for denial in almost every case, there are rare exceptions, must match the original denial rationale. Standard language for appeal to the IRE must be included. And again, once forwarded to the IRE, the Plan cannot reopen. This is outside the Plan’s jurisdiction.

We have been seeing – at least I have been seeing – a certain trend where Plans reopen cases after referral to the IRE and approve them to reduce their overturn rate. That’s not acceptable.

Tiering Exception – The standard has been and is that there is a drug in a similar class at a lower tier to be appealed to within the structure – a non-preferred brand for a preferred brand in general

– and the lower-tiered drug has been tried and failed. The Denial Letter must explain this and be specific to it because it's not obvious.

Direct Member Reimbursement – I'm going over this because mistakes tend to be made. There are three incidences. One is an urgent, out-of-network request for a formulary drug and must be approved or denied based on the reasonableness of the urgency. Urgent out-of-network payment for an off-formulary or a PA drug – In this case, it's not only urgency; it's whether a coverage determination for this drug would have been approved had it become antique. This is a coverage determination process, and it should be treated as if the CD was filed before adjudication. And then there's also the rare case of an urgent, in-network payment for an off-formulary drug which again needs to be adjudicated as if a coverage determination was filled. The patient has similar rights to appeal, and the process for the redetermination and reconsideration are identical. In the end, by the way, we also like to see the end of the decision processes evidence that a drug was provided in a timely manner or that an alternate was provided in a timely manner.

I'm going to go to Organizational Decisions, which are very similar to Coverage Decisions except there are four variations in service and, again, equal requirement for Plan outreach. There's in-network, out-of-network, pre-service, and post-service.

Pre-service Out-of-Network Care – The Notice of Denial of Medical Coverage – the NDMC – should explain the out-of-network status of the service and redirect the provider or the patient to a provider, preferably by name, who is in network. In the rare circumstance that an out-of-network provider is required – for example rare surgery for asymmetric septal hypertrophy – that this must be referred to and the Plan needs to arrange coverage.

Communication with the referring in network provider in general is helpful to prevent further events. Most of the out-of-network pre-service requests don't come because of a beneficiary error. It comes because of a provider error referring to an out-of-network care. And this should be part of the communication strategy with your network.

For example, out-of-network cataract surgery: "We are unable to approve your request for cataract surgery from Dr. A. because this specific surgery is available in your network from several providers listed below, with phone contacts listed as well. These providers are now scheduling new appointments. If you wish to appeal this decision... etc."

Post-Service In Network Care – There is no beneficiary liability for in network care beyond standard cost sharing. Any Plan directed care becomes a coverage service in terms of beneficiary liability. For example, a beneficiary who's Plan PCP provides two annual wellness visits in a 12-month period -- while the provider may be at risk, the beneficiary is not. Any Notice of Denial of Payment for Plan directed care must be specific so an enrollee receiving this understands that they are held harmless. An EOB that's used as a Notice of Denial of Payment needs to have clear language explaining that the beneficiary is not held harm – in fact is held harmless – for the cost. And appeals language should be clear that the application only relates to in-network cost sharing because there is not a complete denial of Plan directed care. And communications with in-network providers concerning need for prioritization may help to avoid this issue.

To re-emphasize, if the EOB is used as an MDP, the denial coding must clearly indicate there is no patient liability for post-service in network care.

Post-service Out-of-Network Care – There are two categories, Plan directed and Non-Plan-directed. Plan directed care should be treated as in network. There is no beneficiary liability. Plan directed care by the way includes out-of-network referrals by in network providers – a blood sample sent to an out-of-network lab or a referral to an out-of-network specialist.

Non-Plan-Directed, self-referred, and urgent care must be evaluated using a prudent layperson standard. Emergency ward visits and hospital admissions need to be evaluated from the impacted enrollee's positive. The Notice of Denial of Payment, if appropriate when issued, must be clear in terms of reason for denial. From our Guidance, a detailed rationale about why a service is not covered, and the rationale must be specific to each individual case and written in a manner that an enrollee can understand.

To recap, any scenario in which an enrollee is transferred by ambulance to an emergency ward, evaluated, and admitted for treatment must be evaluated with a prudent layperson's standard of what a reasonable patient in that circumstance could assume and consider in terms of communication and transfer.

Non-urgent Notice of Denials of Payments must explain the specifics of alternatives that were available. For example, out-of-network evaluation for chronic back pain: "We are unable to approve payment for the submitted claim for the outpatient visit on July 9, 2012, and radiology services on July 11, 2012, for treatment of your back pain. These services were performed by out-of-network providers, Dr. A. and Radiologist Associates B. There are several orthopedic surgeons in your network including (names) who are scheduling new patients at the present time, as well as in network imaging centers including (names). Please discuss further care needs for this medical problem with your primary care doctor if you wish to appeal."

The pre-service in network cases are probably the most complicated ones because the decisions need to be based on national coverage decisions, local coverage decisions, and local max standards of care. The clinical criteria to support evidence of medical necessity must be available on request and on audit. The key element – and the absolute key element – is outreach to providers to assess clinical rationale for the service and the alignment with coverage criteria. The Notice of Denial of Medicare Coverage must be in plain language, specific to the case at hand, with adequate information to allow reconsideration of request. The clinical criteria for reasonable and necessary needs to be based on fee-for-service standards. Changes in site of care may be permitted when clinically appropriate, but RNN restrictions beyond those in the CDs are not.

To re-emphasize, pre-service in network organizational terminations cannot be adjudicated without contact with the ordering physician. Non-response is never a reason for denial in an MA Plan as the physician represents the Plan to the beneficiary. The Plan Medical Director is, again, responsible for gathering adequate information.

We really never like to hear a complaint that the doctors don't respond to us because the doctors are you in in network cases. The Notice of Denial of Medicare Coverage must have adequate information for appeal. For example, the use of home nesiritide infusions: "We are unable to

approve your request for at home infusion of the drug nesiritide natrecor for chronic heart failure. We have discussed this case with your physician, and nesiritide is not a Medicare covered service when provided in the home. Please discuss alternative treatments with your physician if you wish to appeal, etc.”

Or, bariatric surgery Roux en-Y gastric bypass: “We are unable to approve your request for gastric bypass surgery because patient information received from your physician do not meet Medicare criteria for this operation. Medicare covers this service for morbid obesity, defined as a body mass index greater than 35 which would be equivalent to 290 pounds at your recorded height, in the setting of another related condition, such as diabetes, after failure of medical treatment for weight loss. Please discuss alternate approaches with your physician if you wish to appeal.”

The Notice of Denial of Medicare Coverage for services ordered by a Plan physician must explain in plain language the reason for Plan disagreement physician and the next steps. Partial denials have the same information. Without contacting the ordering physician, it’s impossible to have adequate information for a decision almost always.

Redeterminations – separate review with expertise, a second chance for outreach to gather information, and an automatic referral to the IRE if negative decision. And once again, when it goes to the IRE, it is out of a Plan’s jurisdiction.