A GENERAL GUIDELINE PRINCIPLES

The principles summarized in this section are key to the intended application of the New York State Medical Treatment Guidelines.

Medical Care

A.1 MEDICAL CARE

Medical care and treatment required as a result of a work-related injury should be focused on restoring functional ability required to meet the patient's daily and work activities and return to work, while striving to restore the patient's health to its pre-injury status in so far as is feasible.

A.2 RENDERING OF MEDICAL SERVICES

Any medical provider rendering services to a workers compensation patient must utilize the Treatment Guidelines as provided for with respect to all work-related injuries and or illnesses.

A.3 POSITIVE PATIENT RESPONSE

Positive results are defined primarily as functional gains which can be objectively measured. Objective functional gains include, but are not limited to, positional tolerances, range of motion, strength, endurance, activities of daily living, cognition, psychological behavior, and efficiency/velocity measures which can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation.

A 4 RE-EVALUATE TREATMENT

If a given treatment or modality is not producing positive results, the provider should either modify or discontinue the treatment regime. The provider should evaluate the efficacy of the treatment or modality 2 to 3 weeks after the initial visit and 3 to 4 weeks thereafter. Reconsideration of diagnosis should also occur in the event of poor response to a rational intervention.

NYS MEDICAL TREATMENT GUIDELINES (MTG) UNDERSTANDING VARIANCES

Slide 1

Hello, my name is Dr. Elain Sobol Berger. I am the Associate Medical Director and Senior Policy Advisor at the New York State Workers' Compensation Board. Our topic today is the New York State Medical Treatment Guidelines: Understanding Variances.

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The intended audience for this course is medical providers who are responsible for the diagnosis, treatment and management of patients with work-related injuries of the mid and low back, neck, shoulder, and knee.

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Our goals today are to:

- Understand what a variance is, and when it is appropriate to request one;
- To learn the documentation necessary, including the applicable Medical Care
 General Principles, to support a variance request;
- Understand the procedure for requesting a variance;
- Additionally, understand the procedure for requesting a review of a carrier's denial of a variance;

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- Recognize the importance of complete and accurate completion of MG 2 forms to ensure timely and appropriate care for patients;
- Learn the differences between the variance and preauthorization processes and when each should be used;
- And finally, identify board resources that are available to assist with questions regarding variances.

We will use case studies to help demonstrate some of the issues and criteria that apply to variances.

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Before proceeding with some of the other CME information, I would like to provide a quick overview to help set the stage for our discussion today. In March 2007, the New York State Legislature passed workers' compensation reform legislation. This legislation represented a major change in the workers' compensation system, and some would say that this is probably the most significant change in New York's Workers' Compensation System ever. Governor Spitzer gave responsibility for developing new medical guidelines for injured workers to the State Insurance Department, asking that a task force and an advisory committee be formed to develop new guidelines. The committee developed proposed guidelines for the back, neck, shoulder, and knee. The Medical Treatment Guidelines went into effect on December 1, 2010.

Variances represent the intersection between the actual Medical Treatment Guidelines and implementing regulations. In order to effectively care for injured workers, it is key for physicians to understand the Medical Treatment Guidelines and regulatory processes as they apply to variances.

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This activity has been planned and implemented in accordance with the essential areas and policies of the Medical Society of the State of New York through the joint sponsorship of MSSNY and the New York State Workers' Compensation Board. MSSNY is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Medical Society of the State of New York designates this enduring material for a maximum of 1.0 AMA/PRA Category 1 Credits. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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I have no relevant financial disclosures.

The Medical Treatment Guidelines adopted by the New York State Workers'
Compensation Board are the standard of care for injured workers for the identified body parts: the low back, the neck, the shoulder, and the knee. They are evidence-based using the strongest available medical studies; and, in the absence of strong medical evidence, consensus was developed by experienced medical professionals who participated on the Task Force and on the Advisory Committee.

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The Medical Treatment Guidelines are mandatory and apply to all treatment, which means any date of service on or after December 1, regardless of the accident or injury date. They do not apply to emergent or urgent care, and care that is urgent or emergent should continue according to the standards that are clinically appropriate.

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I look at the variance process from two prongs. The first prong is the actual Medical Treatment Guidelines and the general principles, and the second prong is the regulatory processes. What I'd like to do here, in slide 10, is to very briefly walk you through the general principles. The Medical Treatment Guidelines contain 23 general principles. These principles are key to interpreting the Medical Treatment Guideline recommendations and actually provide a framework for documenting medical necessity. They assist in providing guidance for identifying goals and outcomes of treatment. And they are located in the first section of each Medical Treatment Guideline.

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The general principles tend to be overlooked, so I'm giving them a special mention here. And, I'm going to focus on four of the general principles. The four that we are going to look at are:

- Medical care;
- Rendering of medical services;
- Positive patient response; and

Reevaluation of treatment.

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First, I'm going to delve into the regulatory component of the variance process. I think it's important that physicians understand what the regulations say, and having an understanding of what the regulations require will allow the physician to use the Medical Treatment Guidelines and apply the Medical Treatment Guidelines to meet the criteria of the variance process. Variances are addressed in the Workers' Compensation Law, and I've identified the section for you. The regulations actually define:

- Who can request a variance?
- What is a variance?
- When is a variance permitted?
- What is required?
- How to request a variance?
- How to obtain review of a variance denial?

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The variance regulations define who is a treating medical provider. And, I mention this because there has been some confusion about the term 'treating medical provider'. Within the variance process, a treating medical provider is considered a physician, chiropractor, psychologist and podiatrist. Under these regulations, a physical therapist or occupational therapist are not treating medical providers. What this means, practically, is that the physical therapist himself or herself may not request a variance. The therapist has to work in coordination with a physician or a chiropractor in order to begin a variance process. The documentation that the physical therapist may perform in his or her assessment can be utilized by the physician to request a variance.

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What is a variance?

A variance is an exception or a deviation from the Medical Treatment Guideline recommendations. The variance was put into effect in recognition of the fact that people

heal at different rates, and there may be extenuating circumstances or co-morbidities that may delay an individual's response to treatments or procedures. And, a very good example here is somebody who may have a co-morbidity of cardiac disease or pulmonary disease and is moving along slowly in their treatment, but needs to have more time because of the co-morbidity. A variance may be requested to extend treatment beyond the treatment durations listed in the Medical Treatment Guidelines. Another reason that a variance may be appropriate is that new literature may come out that may demonstrate the effectiveness of novel treatments or new treatments that may be appropriate for a particular patient. And in this case, peer-reviewed studies may provide evidence supporting new or alternative treatments. As an aside, I need to mention one of the things that we have seen at the medical director's office is the use of YouTube demonstrations for peer-reviewed evidence. Many people may laugh, but this would not be considered peer-reviewed evidence. We are talking about peer-reviewed journals that have gone through the vigorous review process.

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The variance allows, in essence, flexibility and care. The physician needs to make a determination that care that varies from the Medical Treatment Guidelines is appropriate for this patient and is medically necessary.

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When is a variance permitted?

The regulations identify three circumstances when a variance may be necessary or indicated. And the three situations are:

- When a physician is treating outside of the recommendations of the Medical Treatment Guidelines;
- Where a condition, a treatment or a diagnostic test is not addressed or covered in the four Medical Treatment Guidelines; and finally
- When requesting an extension of therapy beyond the maximum duration recommended in the Medical Treatment Guidelines.

The regulations go on to give us the required information in order to request a variance. All variances must include a medical opinion that states:

- The basis for the proposed care;
- Why the physician believes it is medically necessary and appropriate to deviate from the Medical Treatment Guidelines for this particular patient;
- An explanation of why Medical Treatment Guideline alternatives are not appropriate or sufficient; and

If a variance is requested for treatment that is not recommended or not covered in the

• A statement that the patient agrees to the proposed care.

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Medical Treatment Guidelines, the physician needs to identify the signs or symptoms that did not improve when care was provided in accordance with the Medical Treatment Guidelines. The physician may submit citations or copies of relevant literature in published, peer-reviewed journals to support the variance request. We recently had a case that was referred to the Medical Director's office. The physician requested care that was not covered and/or not addressed by the back treatment guideline. If we look at the requirements, all variances would have to have an explanation of why Medical Treatment Guideline alternatives were not appropriate or sufficient for this patient. In the particular case at hand, the physician-supportive documentation indicated that other alternatives that are recommended in the treatment guidelines were being considered and planned. So for example, epidural steroid injections were a consideration and were being set up for the patient. So this particular criteria out of the regulation was not met. In addition, the physician provided a long list of citations and references, but they all applied to cancer/chemotherapy-related literature. This literature did not support the particular situation for this patient who had a diagnosis of low back strain or sprain, and cancer/chemotherapy would not be relevant literature to support a variance request in this situation.

We addressed the requirements for a variance request for care outside of the Medical Treatment Guideline recommendations and for care that was not covered in a Medical Treatment Guideline. The last variance request is a request for therapy beyond maximum duration. This is the most commonly seen request at the Board. And basically, the provider needs to document that the reason a request for treatment - beyond the maximum duration - is being made is because the injured worker continues to show objective functional improvement and is expected to continue to improve with additional treatment.

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I'm going to go into the four general principles that are important for documentation, particularly in this case, documentation to request treatment beyond the maximum duration.

Principle #1 says that medical care and treatment must be focused on restoring function to meet daily and work activities and return to work. This documentation, when provided, relates to ultimate goals. What's the overall outcome that is anticipated or is required as a result of the ongoing therapy and/or treatment? And clearly stated, the end point would be that the patient should be able to meet daily and work activities and return to work. This the end point of care.

Of note, principle #2, which is not specifically discussed here, reinforces the concept that the Medical Treatment Guidelines are the standard of care for injured workers for the four covered body parts.

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General principle #3 talks about the outcomes of treatment and care as a patient moves through the therapy treatment plan. And it's generally called "positive patient response" or it's defined, primarily, as objective functional gains which can be measured.

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General principle #3 goes on to give more detail on what we mean by objective functional gains and they include, but are not limited to, improvement in position, range of motion,

strength, endurance, activities of daily living, not just a few degrees of range of motion. We need to be able to link these improvements to some functional gains or functional improvement that's bringing us along the continuum to the ultimate goals.

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In looking at a patient's positive response, patient's positive responses are not enough to warrant objective functional improvement criteria. The patient's complaints can be considered as part of a whole clinical picture; but in and of themselves, they would not meet the goal of an objective functional improvement.

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Principle #4 requires the re-evaluation of patient treatment. The slide indicates what the regulation requires, as well. Two-to-three weeks after an initial visit and three-to-four weeks thereafter, the physician needs to re-evaluate what the patient is doing. If the patient is doing well, then the treatment plan can continue.

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If the treatment plan is not producing positive results, then the provider should either modify or discontinue the treatment regimen or perhaps go back and reconsider the original diagnosis, in the event of a poor response to what would be considered a reasonable intervention.

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How do we document objective functional improvement? This is a key slide and provides information that seems to be missing from many of the variance requests that we have seen in the Medical Director's Office. Objective functional improvement, basically, has three components:

- An initial evaluation Where was the patient at baseline, either pre-injury or at the initial evaluation or assessment?
- Number two, re-evaluation now What is the patient doing now in comparison to a previous therapy session?

- And finally, goals. And goals, I divide into long- and short-term.
 - A short term goal is where do you expect the patient to be at the next evaluation?
 - What type of treatment is planned in order to help the patient reach the short-term goals?

And finally, the ultimate goals. These will evolve as the treatment progresses, but should always be focused on return to work, work activities and identified limitations, and links us directly to general principle #1.

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The burden of proof is a term that comes out of the regulation and is important for physicians to understand. This represents the intersection of the documentation that's provided by the physician, based on the Medical Treatment Guideline recommendations and general principles and the requirement that the doctor define medical necessity and appropriateness of the variance request. Oftentimes, what we see is that the doctor will make a statement of medical necessity, but the history and exam findings either don't support the statement or actually conflict with the statement of medical necessity.

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The variance request needs to be on Workers' Comp Board form MG–2. If there's more than one treatment that's being requested, the addendum MG-2.1 should be used to request additional treatments in addition to the original request. These next bullets help to point to problems that we have seen in terms of complying with the process requirements. Forms need to be filled out correctly and accurately. A Medical Director's Office bulletin was put together to address the issues of inaccurate or incomplete forms. Inaccurate or incomplete forms can result in either a denial of care or having to redo the MG-2 form and start from scratch. So, provide the information, in particular, the documentation of medical necessity and the supporting documentation to demonstrate the burden of proof that your request is, indeed, appropriate. The forms need to be sent to the carrier and the Workers' Compensation Board. The carrier has 15 days to respond to the variance request with either approval or denial. The exception to that is when the carrier would like to obtain an IME or

independent medical examination. Then the carrier has five days to notify the patient of the intent to obtain an IME, and 30 days to complete the IME review. That IME review can be a record review or could be an actual examination.

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This next slide is very important. A variance must be requested before the care that varies from the Medical Treatment Guidelines is performed. If the care is done and the variance has not been approved, the carrier does not have to pay for the care provided.

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What happens if the carrier denies the variance request?

The physician has the ability, within eight days, to informally discuss the variance request with the carrier. Hopefully, this would result in a resolution and an agreement on the variance request and then the carrier would issue an approval based on the informal discussion between the physician and the carrier. However, if the informal resolution is not successful, then the treating medical provider has to go back to his patient and discuss whether or not the care is, indeed, still appropriate. If it is, indeed, appropriate, the patient can then request a review of the variance denial.

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The patient has 21 days to request a review of the denial, and there is a section on the MG–2 form that the patient and/or the patient's lawyer completes to indicate that they are requesting a review.

There are two approaches to obtaining a review. One is the expedited hearing, and that would occur in front of an ALJ, an administrative law judge. The judge would review all the information that was provided and determine whether or not the burden of proof had been met and then would make a determination as to whether or not the variance denial should be reversed. An alternative approach is medical arbitration by the Medical Director's Office. The Medical Director's Office was set up to assist in implementation of the Medical Treatment Guidelines. There are two physicians and five nurses who are members of the Medical Director's Office. They have a process for reviewing the variance

denial. They review the medical information and make a determination as to whether or not the burden of proof has been met. The determination that's made by the Medical Director's Office is final and binding. There is no appeal from that. The determination from the hearing can be appealed and can be moved onto higher levels of the court system. With the Medical Director's Office, a denial though can be another MG-2 can be put forward providing the missing information and, that can move pretty quickly through the system as well.

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I've given you the information on the two components, the Medical Treatment Guidelines, recommendations, criteria and general principles that a physician needs to know; and I have given you the regulatory components of the variance process. In this following case study, I'd like to show you how these two intersect and apply the information that has been provided in this discussion.

So let's start with case #1. By the way, these cases have all come from cases that the Medical Director's Office has reviewed. We've clearly removed any identifying information and we just are using these cases as examples of the types of cases that are being seen in the Medical Director's Office. Similar cases are being seen and heard by the administrative law judges. Let's start with the variance request to continue physical therapy and acupuncture. And in this case, we have a 46-year-old man with a 6-year-old low back injury. He's been receiving physical therapy and acupuncture for years. He's not working.

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The statement of medical necessity from the physician simply states that the physical therapy and the acupuncture are needed for abdominal pain and low back pain. The physical therapy notes, which are included, essentially are unchanged when comparing notes from 2006 through 2011. There is no evidence of any functional improvement.

Nothing has changed as far as the patient's clinical situation. The request is for physical therapy three times a week and acupuncture three times a week. The goals that are

identified are decreased pain, increased range of motion and strength. None of these are specific goals with specific criteria; and if you remember, when we look at the documentation requirements, these are very general types of goals that are not specific to the patient and are not linked to the ultimate goal of restoring function, return to work, and daily activities. The treatment plan was a laundry list of modalities.

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If you look at the treatment plan on the next slide, you will see a long list of virtually every potential modality. None of them are linked to a particular success or a particular objective improvement for the patient, and there is absolutely no documentation provided to show whether any of these particular or specific treatments are effective or not. Interestingly enough, in the last sentence, the provider puts in that there's going to be a re-evaluation within six weeks or thereafter. However, there's no reevaluation as required by the regulations and by the general principles.

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If we look at what the requirements are, we want the positive patient response or objective functional gains. This is the type of documentation that we would like, objective measurements, which may include physiological and anatomic changes and the functional impact or outcomes related to the treatment and to work activities. These objective functional gains, as I previously mentioned, become your short-term and long-term goals.

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And once more, I'm putting in the slide that outlines what the requirements are for documenting objective functional improvement. All of these are missing from the case study #1. We don't have a baseline. We don't have a clear definition of where the patient is at this point in the continuum of his treatment, and we don't have clear goals, short-term nor long-term goals, identified. This is a variance that would be denied.

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Of note, the denial would probably reference lack of meeting burden of proof by the provider.

Case Study #2 is a variance request to continue physical therapy and is the case of a 62-year-old man who has an 11-year-old low back injury. He's working and he's been receiving physical therapy for 10 years.

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The statement of medical necessity from the physician to continue physical therapy reads "patient is making slow progress, able to reduce medication usage, should continue PT before considering alternative treatments, specifically "identified injections."

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The accompanying documentation to support the variance request shows the patient is actually worse. The MD progress note states worsening pain. The treatment plan: needs new MRI because of worsening symptoms, and identifies pain, weakness, and numbness, is recommending an EMG, is suggesting adding the narcotic to the pain regimen, and is also referring patient for a lumbar ESI.

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In this case, if we look at general principle #4, if a treatment is not producing positive results, the provider should discontinue or modify the treatment regimen or even reconsider the diagnosis. And here, the request is to continue physical therapy which, according to the supportive documentation, does not seem to be producing positive patient outcome. The burden of proof for a variance request to continue PT has not been met by the physician.

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Case study #3. We have another variance to continue PT. In this case, we have a 60-year-old woman who had a low back injury six months ago. She's not working. She had a discectomy performed in May 2011, one month before the variance request came in.

In the variance request dated June 2011, the primary care physician requests continuation of physical therapy. The statement of medical necessity by the primary care physician goes on to state "back pain continues and patient needs to continue PT for strength and stability." However, in the primary care doctor's note, there's no mention of the fact that the patient had surgery about one month ago. The patient has not received physical therapy since the surgery.

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In this case, a variance is not required for post surgery physical therapy and PT would be consistent with the Medical Treatment Guidelines. If, in this case, the maximum duration of therapy was approaching and the patient was continuing to demonstrate a positive response and improving, then the physician might want to request a variance if the patient agrees to further treatment. The variance should be requested as soon as the doctor believes recovery is proceeding slower than expected.

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Next is case study #4, and this was a variance request, not to extend treatment beyond maximum duration, but to treat outside of the Medical Treatment Guideline recommendations. And, the request was for an MRI of both knees. The statement of medical necessity from the physician informed us that the reason for this testing was to decrease headache, neck, lower back, left buttock and radicular upper and lower limb pain, improve range of motion. MRI to both knees to rule out internal derangement of knee. In the doctor's note, the history addresses back and neck injuries. There's absolutely no mention of knee complaints or problems. In the examination, the only reference to the knee is part of a neurological exam and discusses only the fact that the knee jerks are bilaterally symmetrical. In the assessment and the treatment, there is no mention of a knee diagnosis or underlying knee problem under consideration.

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The physician must provide documentation that the medical care that varies from the

Medical Treatment Guidelines is indeed appropriate and medically necessary. And in this case, the burden of proof to demonstrate that the variance request to treat outside of the recommendations has not been met.

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In the next few slides, I would like to address an issue that's related to variances and has actually raised a lot of questions. I thought it might be worthwhile to discuss the C-4 authorization and compare that to the MG-2 and differentiate when each should be used and why each is in place. With 13 very limited exceptions that are clearly identified in the treatment guidelines, all medical care that is provided, consistent with the Medical Treatment Guidelines, is considered preauthorized. This is a major change from how care was provided before the reforms went into place. When an injured worker requires one of the 13 procedures that needs preauthorization, the physician needs to complete a C-4 AUTH form. The Medical Treatment Guidelines give criteria that must be met for the prior authorization for these procedures.

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The MG–2 form, as we discussed, is used when a physician wants to treat outside of the Medical Treatment Guidelines and cannot be used to obtain preauthorization. Again, the C-4 AUTH is needed when any of the identified procedures that require preauthorization is being considered or contemplated. The C-4 AUTH cannot be used to obtain preauthorization for treatment that is considered consistent with the Medical Treatment Guidelines. As a side note, when providing care that is not covered by a Medical Treatment Guideline, there are circumstances when the C-4 AUTH might be used. But that is outside the purview of this discussion today.

The procedures that require preauthorization and thus require completion of the C-4 AUTH form are listed in the next three slides. Essentially, these procedures were identified because of the potential for overuse and/or abuse and therefore, preauthorization is in place as a way to ensure that appropriate criteria were applied when these procedures were requested. Procedures that require preauthorization and, therefore, a C-4 AUTH form include lumbar fusion, artificial disc replacement, spinal cord stimulators, electrical bone stimulation, vertebroplasty, kyphoplasty, anterior acromioplasty,

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Chondroplasty, autologous chondrocyte implantation, osteochondral autograft, meniscal allograft transplantation, knee arthroplasty, either a full or partial knee joint replacement.

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There is a preauthorization required when repeat surgery is being considered and it's abbreviated as repeat or duplicative surgery. And of note with this particular preauthorization requirement, it comes into play only if the Medical Treatment Guidelines do not address repeat procedures. So, for example, if somebody is going to do epidural steroid injections, they are listed as being potentially useable three times. So if you're going to do repeat ESI, you would not fall under this requirement. But if you were going to be doing repeat back surgery, for something that would not normally require a repeat surgery, this prior authorization would be necessary.

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I'd like to summarize what we've discussed today and package it so that we have some take-away points. In summary, variances allow for flexibility in care. The regulations identify three circumstances when a variance is permitted and identifies the documentation necessary to support the variance. Keeping in mind that the criteria for that documentation are found in the Medical Treatment Guidelines and the general principles. And again, the three situations when a variance may be appropriate are:

• When a provider wants to treat outside recommendations in the treatment

guidelines,

- When the condition or the treatment is not discussed or addressed in one of the four
 Medical Treatment Guidelines, or
- When requesting an extension of therapy beyond the maximum duration recommended in the treatment guidelines.

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When a physician makes a determination that the medical care that varies from the medical treatment guidelines is appropriate and necessary, a variance should be requested. And the physician is responsible for providing the documentation necessary to support that variance request.

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In providing the documentation or in meeting the burden of proof, the physician needs to look at the Medical Treatment Guidelines, review the criteria, and apply the general principles. Medical care and treatment should be focused on restoring functional ability to meet daily and work activities. There should be a positive patient response with functional gains which can be objectively measured.

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There must be reevaluation of the efficacy of treatment. Importantly, if treatment is not producing positive results, the provider should modify or discontinue the treatment regime or reconsider the diagnosis.

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Finally, let me address the resources that the Board has made available to help physicians and other providers in addressing questions and concerns about the variance process. The Board's website, which is listed on the slide, if you go to that website and go to "Healthcare Information," you can actually click on each of the Medical Treatment Guidelines. You can look at the general principles, review the recommendations. There is also a link to the Medical Treatment Guideline training programs. This is an overview of the four Medical

Treatment Guidelines and a program with CME credits. There's also a physical therapy case study to assist physical therapists in understanding the need for objective functional improvement and defining some of the criteria. Frequently Asked Questions have been utilized a great deal by many providers and answer some of the issues that have been recurrent. I indicated that there was an MDO Bulletin on how to complete the MG–2 forms. There are other MDO Bulletins and more coming as issues come up that need clarification.

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And finally, probably the resource that would be most helpful is the Medical Director's Office. The contact information is 1-800-781-2362. I've also given you the e-mail address. Our nurses are available to answer questions. The best approach is an e-mail and we will respond to your questions and concerns, clarify information. When we get variance requests, we do sometimes reach out when we need clarification. And don't hesitate to call upon us, because we would like to assist, as we see this as a way to help patients get the care they need as quickly as possible. And finally, there is a brochure for the injured worker called, *Get the Facts*.

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And, the last piece of information is, how do you get your certificate for CME credits after completing this course? To receive a certificate of completion and your continuing medical education credits, you must complete the following program evaluation.

Thank you very much.