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Patient Safety: Restraint Standards

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Restraints as Deterrents to Falls and Injury

The use of physical and chemical restraints has long been accepted as standard practice when aimed at preventing falls and injuries in hospitalized patients and long-term care residents. However, recent studies have demonstrated that restraints do not necessarily prevent injuries. In fact, physical restraint use has been associated with such adverse outcomes as pressure sores, strangulation deaths, decreased mobility, increased agitation and depression. Often there is no increase in serious injury when physical restraints are replaced with other less restrictive safety measures based on the individual's specific needs. A restrained patient who falls is more likely to sustain a more serious injury than one who falls while unrestrained.

Restraint Standards

Rising concerns over injury, death, loss of dignity and independence among restrained patients in both long-term and acute care facilities prompted regulatory agencies to define the standards of care. Restraint standards span across national, state and local levels.

All hospitals and healthcare facilities receiving Medicare and Medicaid reimbursement must comply with specific standards outlined by the Health Care Financing Administration (HCFA, now known as Centers for Medicare and Medicaid Services) and The Joint Commission of Accreditation of Healthcare Organizations (JCAHO). Restraint care may also be guided by state code such as in North Carolina Administrative Code, Section 3302R: "The patient has the right to medical and nursing treatment that avoids unnecessary physical and mental discomfort".

The Joint Commission of Accreditation of Healthcare Organizations defines physical restraints as "any manual method of physically restricting the patient's movement, or normal access to his/her body, material, or other equipment, attached or adjacent to the patient's body that (s)he cannot easily remove."

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What you always Wanted to Know about Medicare Set Asides but Were Afraid to Ask

Pattie Patterson RN, LNCC, Life Care Planner, MSA Allocator

Medicare Set Aside (MSA) actually affects not only worker's comp injuries but motor vehicle accidents and personal injuries, i.e. injuries involving liability insurance, no-fault insurance and uninsured motorist insurance, but in this article I will be speaking only to the worker's comp injuries, just to not confuse the article, although the others have the same criteria for submission to CMS (Center for Medicare and Medicaid Services).

In 1980 the Medicare Secondary Payer (MSP) statute was created as part of the Omnibus Reconciliation Act (OBRA) to ensure that Medicare was only secondarily responsible for payment of medical expenses for persons covered by Medicare who were also covered by another type of private insurance. This means if a worker is injured in a work related accident and this same worker meets certain criteria, then the settlement must be approved by CMS in order to assure that CMS's interests are being served.

What Exactly is a MSA?

MSA is a designated amount of the entire settlement that is set aside to pay for medical services and/or supplies that would normally be paid by Medicare were it not for the insurance involvement. These allocated funds are to be used to pay only the items that would normally be paid by Medicare. As long as Medicare approves the amount and the beneficiary is compliant with its terms, there is no danger of CMS refusing to pay if, for some unforeseen circumstance, the funds are exhausted before the end of the beneficiary's life.

Criteria for Submitting a Claim to CMS

There are two classifications for submitting to CMS

- Class I - The individual is a Medicare beneficiary at the time of the settlement regardless of the amount of the settlement.
- Class II – The individual is not currently a Medicare beneficiary at the time of the settlement but:
  - The total amount of the settlement is over $250,000.00 (including attorney fees and costs) and
  - There is a reasonable expectation of Medicare enrollment within 30 months of the settlement date. This can be a reasonable expectation if the individual:
    - Is 62 ½ years of age.
    - Has applied for SSD (Social Security Disability) benefits.
    - The individual was denied SSD benefits but anticipates appealing.
    - Is in the process of appealing or refilling.
    - Has end stage renal disease and is not yet on Medicare.

For any client who falls within these criteria, a claim must be filed to CMS for approval before you settle the case, or it could back and bite you and/or your client later on down the line.

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Patient Safety: Restraint Standards

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Under JCAHO guidelines, healthcare facilities are required to determine their own systematic approach for restraint use. Because restraints are considered a form of medical treatment, they can only be used under the direction of a physician. In ordering the use of restraints, the physician must specify the medical reason for using the device (i.e., confusion, prevention of removal of tubes and lines), the type restraint (i.e., wrist mittens, vest, side rails) and the length of time over which it can be used. Restraint use must be carefully monitored and documented, and its effectiveness must be continuously evaluated. An effort must always be made to use the least restrictive available method of restraint, and to restore each individual to his or her maximum possible level of independence.

In acute care facilities, restraints are either for acute medical-surgical care or for behavioral management. Each category has its own specific restraint care guidelines for physician prescription, restraint selection, assessment, and ongoing monitoring. An example of restraints used for acute medical-surgical care may be immobilizing the hip and arm to prevent a confused patient from getting out of bed unassisted and removing an IV line after a hip replacement. A registered nurse may initiate a physical restraint based on professional nursing judgment. A verbal or written order from the physician must be obtained within 12 hours of the initiation of the restraints. According to JCAHO standards the physician must be notified immediately if the initiation of the restraint is a result of a change in patient condition. Patients in restraints must be monitored at least every 2 hours. If the ongoing patient assessment indicates a clinically justifiable need for continued restraint use in acute medical-surgical care patients, then the order for restraints must be renewed each calendar day. While JCAHO has set minimum standards for restraint care, hospital policy may actually mandate a higher frequency of assessment and monitoring of restrained patients.

The behavioral restraint management standard applies in emergency situations where the patient's behavior has become violent or aggressive and the least restrictive method to assure patient safety and/or the safety of others is a restraint. A registered nurse may initiate the restraint, but a physician must make a face-to-face assessment within one-hour of the initiation of the restraint. Chemical restraints are also considered restraints for the purposes of behavioral management. A drug is used as a restraint when it is used to control violent or aggressive behavior or to restrict the patient's freedom of movement and is not considered standard treatment for the patient's medical or psychiatric condition. Restraint assessment and monitoring frequencies are also determined by patient age. The younger the patient, the more frequent the assessment should be.

Side Rails as Restraints

In 1995 the Food and Drug Administration (FDA) issued a safety alert, citing concerns of entrapment, injury and strangulation death resulting from the use of side rails. Between 1985 and 1999, the FDA received 371 reports of patients caught trapped, entangled or strangled in hospital beds. Of these mostly frail, elderly or confused patients, 228 died as a result.

To date, no research study has demonstrated that the use of side rails prevents injury as a result of a fall. In fact, a patient who falls from a greater height while climbing over a side rail is more likely to be seriously injured than one who falls from the bed mattress.

HCFA (CMS) defines restraints to include side rails as well: any device that restricts a patient's voluntary movement or access to his body and that can't easily be removed by the patient. Most healthcare facilities now use beds that have 4 side rails. A half or quarter-length upper side rail is not considered a restraint if the patient uses it to assist himself into or out of bed. Additionally, 4 half-length side rails are not considered a restraint if the patient requests them and the patient can lower them before entering or exiting the bed.

Alternatives to Restraints

In an effort to use the least restrictive method of restraint available to ensure patient safety and dignity, healthcare researchers have studied and recommended varying alternatives to to physical and chemical restraints. Alternatives may include the following interventions: environmental modification, limiting physical accessibility to lines and tubes, pain relief, reality orientation, anticipation of toileting and hydration needs, distraction, and physiological assessment of factors contributing to confusion.

When reviewing medical records of a restraint-injured client, it is imperative to analyze both the medical and nursing processes that lead to the use of the restraint. Physiologic imbalances that lead to confusion, such as hypoxia (low oxygen levels), electrolyte abnormalities and uremia require prompt medical treatment. Medication regimens that may lead to confusion or toxicity should be carefully examined upon admission. Medications that are usually therapeutic for the elderly patient can quickly become toxic in the face of an acute illness. The need for restraints should be assessed according to institutional and regulatory requirements. Restraint documentation should include: the patient's behavior requiring restraint intervention, immediate physician notification if this is a change in patient condition, the appropriate physician order, response to restraint alternatives, the appropriate nursing observation, assessment and intervention of the restrained patient, the type of restraint, time of application and patient response to the restraint. Negative outcomes (pressure ulcers, contractures and loss of ability to ambulate) associated with restraint use should also be carefully assessed.

Litigation surrounding falls and restraint-injury claims continues to rise. Just as the key to ensuring patient safety is to formulate the plan of care based on the patient's individualized needs, careful analysis of the medical facts will assist attorneys in determining the merits of each individual case.

Case Managers as LNC's

Robert Morrison, RN BSN

The case that has occupied much of my time the past week illustrates the need for plaintiff attorneys to keep nurse case managers close at hand. This case started for us almost two years ago and has been very complicated throughout. We are preparing for court this spring and hoping to bring the patient closure at last.

John (not his real name) is a 48 year-old man who was involved in an automobile accident in 1998 injuring himself and his wife. The other driver was found at fault and ticketed. However, her insurance coverage had not anticipated multiple injuries. The medical treatment was handled through two different insurers during the next four years. Each insurer provided its own nurse case manager, each steering the injured patients through a combination of family practice, neurosurgery, therapy and rehab. His wife's case eventually reached maximum medical improvement (MMI) and was settled by the insurer. John, however, was seemingly stuck in the middle.

Our first order of business was to clearly establish John's current medical status and needs. This was important, as you cannot establish permanent functionality (and thus damages) while the patient remains in active treatment. The goal of treatment is to change and improve the patient's ability and function. You need to make sure that the medical providers have done all they can to advance the patient's condition before you stop. By working directly with all of the doctors involved we were finally able to document a state of MMI in December of 2002. An experienced case management approach was used to bring all three doctors and the patient together to a single understanding.

Next came the need to quantify the patient's damages. You always prefer that they return to their pre-accident state. In this case it wasn't possible, though he did come further than he anticipated in the beginning. An FCE (Functional Capacity Evaluation) was performed to establish his exact level of ability and function. A long and intense two-day evaluation, its basic purpose is to state clearly what the patient can and cannot do, and where their limits are. One of the insurance case managers had this done a year post-accident. However, the results were declared invalid even by the evaluator. It was too early in the course of treatment to do this. He was still regaining his abilities at this point. Even if they had been able to measure exact limits, they would have changed as soon as John progressed to the next stage of therapy.

To make sure all of the individual providers and managers had, in fact, brought John to his maximum state of recovery an Independent Medical Evaluation (IME) was done. This looked at all of the information starting with the accident through the current date. Detailed medical records were provided to the IME physician which showed all of the activity from the various providers. After reviewing all of the information at-hand, this physician agreed that further treatment was unlikely to improve John's situation, and that he did appear to have reached a state of maximum improvement. He also provided a calculated impairment rating to help quantify John's losses as a result of this accident.

Since John had not been able to return to his previous occupation as a truck driver it needed to be established what his occupational situation was. A Loss of Earning Capacity evaluation was done at this point by a certified vocational counselor. This evaluation involved a detailed work and educational history from John covering his entire life. This allowed the counselor to establish what occupations John would be qualified for. Then, by eliminating those whose physical requirements were beyond the limits set in the FCE, the counselor was able to show what possibilities were left. The earning potential of these occupations was compared to that of his prior field of driving a truck. The difference between these figures represented part of the damages suffered by John as a result of the accident.

Now, John's attorney had all of the medical information about his damages. During this time the attorney had been gathering all of John's financial records and pension information. When this had been calculated as a single, supportable figure it was added to the medical damages to make a single settlement package. It is this package that will form the basis of the attorney's courtroom presentation. What the LNC does best is provide a legally astute assistant with a medical background. When you're deciding what nursing backgrounds to have available, don't forget the case manager. Their occupational brief is to bring order to chaos and keep all of the different pieces together in a single, sensible picture.

Medicare Set Asides

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How the Process Works

The MSA Allocator, a person trained in drafting and submitting MSAs to CMS, will collect all pertinent medical information, and establish, from the life care plan how much of the monies need to be allocated to the MSA. Then the Allocater will, with the beneficiary, decide how the funds will be held in trust and who will administer the funds. This can be done by structured settlement annuity, placed in the bank with an executor or both. The Allocator then prepares all of the necessary documents for the proposed settlement and submits these same said documents to CMS for approval. Once CMS approves the settlement it will then need to be finalized. Any negotiations related to the claim must be done prior to the submission of the final proposal, as once CMS approves it, it must stand as is.

Why Should you Submit a MSA to CMS?

The statue allows CMS to expect reimbursement for any and all conditional payments, payments they make while awaiting the settlement. Also, if Medicare has to pay any future medicals on anyone who has received a settlement because Medicare's interest was not protected by submitting a MSA allocation for approval double damage plus interest may be assessed against all parties responsible.

So, the next time you have a case where the client meets the criteria for a possible MSA, do yourself and your client a favor and have a MSA Allocator glean over the records to assure you that you're meeting the burden of protecting Medicare's interest. You'll be glad you did. For more information of other aspects of MSA, please don't hesitate to contact me.

Not Everything Green is Irish in March, OR: Mold, Friend or Foe?

Sarah McLain RN, CLNC, CLCP

Molds are common life forms. They can be found in areas where everything freezes as well as in the tropics where everything is burning hot. They are found in homes and schools and office buildings. They are destructive to many different materials. They can eat away the leather in your shoes. They can eat away wood and wood products. They can invade your body and cause diseases, including allergic reactions, dizziness, sleeplessness and irritability.

To sustain itself, mold releases chemicals into the surrounding moisture, which break down the food source into smaller particles. The food particles mix with the water/juice mixture so the mold can suck it up. One example of how all these things come together for the mold creature is in a forest. Mold grown on dead trees lying in the dark, damp forest. The tree used the sun to create food and then stored that food. When the mold grows on the dead tree it uses the natural moisture of the forest. It burrows into the tree and secretes its juices. These juices eat away the stored food in the tree. Then the mold absorbs this food for its own use. The mold is actually doing us a favor. If it didn't eat away the dead creatures around us (trees, leaves and bugs), we would be drowned in debris. Mold is nature's little garbage disposal.

Mold causes billions of dollars worth of damage to our food supply each year. How many times have you opened your refrigerator and found green spots on your cheese? Did you throw that cheese away? Or did you cut away the green part and eat what was left? Did you get sick? If not, luck may have been with you. The large immigration of Irish potato farmers in the last century was caused by mold attacking the potatoes in Ireland. The Irish people were devastated when their main food source disappeared. Starvation was everywhere.

The place mold has in history is not limited to just the Irish potato famine. Mold is possibly the cause of the mummy's curse in Egypt (the people who went into the tombs got sick and died mysteriously). The symptoms of the people who suffered from the "curse" were similar to those caused by Aspergillus mold. And this mold has been found in the Egyptian tombs. It seems that when the Egyptians buried their dead, they left food so the dead could continue to eat. The mold grew on this ready food source. Mold may have played a part in the Salem Witch Trials. Mold growing on their bread may have caused hallucinations in the children who accused people of being witches. Since the people of that day didn't understand hallucinogenic chemicals, they figured that it had to be satanic influence.

Almost everyone suffers from some kind of mold related problem. Many times, however, the effects are mistaken for something else, such as a headache. Is it a stress headache or did walking into a moldy home give you the headache?

Many people are taken off mood altering drugs after their homes are cleared of mold. Some have actually avoided time in mental institutions by cleaning up their environments. There was one case where the wife was three days away from being committed in a mental institution for severe depression. Her house was cleaned and the mold was removed and her depression vanished. There are plenty of scientific studies which document the mood swings in people exposed to chronic mold.

Even in two paycheck families, children suffer more because they spend so much time in daycare and schools. Because neither of these places tend to be well ventilated, both are notoriously high in mold contamination. Add this to the molds that children bring into the common area from their homes and you can have a killer combination. Most schools and daycares have carpets. The food and glue that kids drop on the carpet feed mold growth. In Sweden, school officials are removing carpets from schools because of the health problems they cause.

The air handlers in many schools are never turned on. Air filters are seldom changed. So mold spores (seeds) float around looking for children's lungs and noses. Adding to the mold problem in schools is the toxic chemical problem. When carpets are cleaned in schools, outbreaks of respiratory disease occurs among school children. The same thing happens in homes. Many carpet cleaners contain formaldehyde, which damages tender lungs.

Almost daily someone is doing a story in the news about a contaminated school and disease epidemics. The classic study on the mold subject is the one in Morbidity & Mortality Weekly Report Jan 17, 1997. This case even appeared on TV. Nine kids in Cleveland, Ohio died from a mold (Stachybotrys chartarum), which was growing in their homes following water problems (leaky pipes, water heaters, etc.) The children died from lung damage caused by mold spores destroying the tender lining of their lungs.

Many childhood illnesses from Attention Deficit Disorder (ADD) to asthma have been reduced or eliminated by getting homes properly cleaned. A few years back very few children had asthma. Today, many children have it. Some teachers tell us that up to 50% of the children in their classes have asthma. One teacher stated that there were more emergency inhalers in her classroom then pencils.

The biggest health problems occur from what mold "gives off". There are chemicals called VOC's (Volatile Organic Compounds) and microscopic spores (seeds), which enter the air and cause various kinds of problems. If you breathe them in, they can cause problems inside your nose. The chemicals can irritate soft mucous membranes inside the nose leading to sneezing and runny nose. If you believe you have a cold, you can treat it incorrectly. What works on a cold or a bacterial infection, won't do a thing to mold infections. If mold spores enter your nose, you can also start having allergic reactions. Again you get the sneezing, runny nose and parts of your body begin to turn red and swell up. Sinusitis and infections can occur when these materials work their way into your sinuses. Millions of dollars are spent each year on over the counter medications to incorrectly treat sinus problems that are caused by mold. If mold products get into your lungs, they can lead to pneumonitis. The tender linings of the lungs have a hard time fighting off mold. The insides of the lungs are warm, moist and have a rich supply of easy to digest material. All the things mold needs to set up housekeeping.

Mold can cause dermatitis. Some soldiers who fought in the South Pacific area in World War II have mold-induced dermatitis to this every day. Ringworm is another skin problem. Ringworm can be very destructive if occurring in places like hair regions. It will actually cut a ring of hair away leaving something that looks like a ring shaped scar. Otitis is a common problem among children. Molds such as Penicillium can wreak havoc with a child's ear. This is both a costly and painful problem. Gastrointestinal distress is a common problem when mold is swallowed. Why would we swallow mold? Simple, it gets in our food in the kitchen. Have you ever found green spots on your cheese? Some people cut this bad part of the cheese off and eat what is left. While this keeps the antacid companies happy, this type of problem costs Americans millions of dollars each year.

Bone infections result if mold gets into the blood and travels to the bone. Usually this occurs when someone has a depressed immune system. But remember, mold can cause a depressed immune system. Mold can cause endocarditis, an infection in the heart, through a surface wound. For example, after getting a tooth pulled, anything growing in the fluids of the mouth goes through the hole in the jaw into the blood stream. Toenail medications are selling in the millions of dollars each year. Toenail fungus causes thick, ugly misshapen toenails, which are almost impossible to clear up. Some molds produce mycotoxins, which can even cause cancer. The most powerful naturally occurring carcinogen is aflatoxin, which is produced by mold.

The fact is that homes are built differently today. And are molds ever glad. To save energy, homes have been built tighter. Indoor air takes 5 times longer to exchange itself with the air outdoors than it did 50 years ago. So toxins and mold products are trapped and Cont on p 5

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concentrated in the home. Add to that the chemicals we spray into our homes that causes all kinds of diseases. We have created a pollution problem in our homes that rivals the most polluted cities in the USA.

If you read the EPA's "Introduction to Indoor air Quality" manual, they tell you to use bleach on "non-porous" surfaces. They tell you to dispose of porous materials contaminated by mold. Cleaning the surface of a mold colony doesn't affect the insides of the colony. Like an iceberg, most of the mold's colony is unseen, below the surface. In our case, below the surface means, "hidden inside the wall, floor or ceiling". And remember, the unseen part of the iceberg sank the Titanic. Most commercial bleaches also leave a phosphate residue, which is like "mold fertilizer". Use of bleach can also lead to the formation of chloroamines, which can cause cancer. In addition, there are studies that show that chlorine bleach is toxic to humans, especially to children. "Technology Review, Jan, 1995 v98 n1 p54(7)".

Some Molds and the Diseases They Cause

- Absidia - Skin eruptions.
- Acremonium - Skin infections as well as meningitis, arthritis and hard palate lesions.
- Alternaria - Skin, ear, nasal and pulmonary infections.
- Aspergillus - Pulmonary infections and blood vessel diseases. Possible cause of King Tut's curse.
- Aureobadidium - Foot and leg infections.
- Candida - Erosive skin infections, yeast infections.
- Chrysosporium - General infections.
- Cladosporium - Skin infections, tinea.
- Coccidoides - Flu like infections and possible brain infections.
- Curvularia - Mycetoma, endocarditis, pulmonary and nasal infections.
- Drechslera - Meningitis, skin and nasal infections, peritonitis, and abscesses.
- Fusarium - Skin, bone, ear infections and skin ulcers.
- Microsporum - Tinea, mycetoma. Mucor - Ear infections.
- Nigrosporum - Skin infections.
- Paecilomyces - Endocarditis, skin lesions, pulmonary infections.
- Penicillium - Skin and ear infections.
- Rhizopus - Ear infections. Scopulariopsis - Skin, lung and ear infections and skin ulcers.
- Sporothrix - Black, hard ulcers of the skin.
- Stachybotrys - Lung disease, especially in children.
- Trichosporon - Beard and mustache infections.

The Unasked Question

By Gail Hendrickson RN, CEN, LNC

A 58 year old male arrives via ambulance to the emergency room. Upon the EMT's arrival at his home, he is complaining of substernal, crushing chest pain, radiating to the left arm and jaw. He is sweaty, and complains of feeling sick to his stomach. His initial vital signs were 180/104, pulse 79, respirations 24, and Oxygen Saturation 98%.

When the patient arrives in the emergency room, the EMT gives his report. He states that he has been in good health. His pain began suddenly, and woke him up. He initially rated his pain a 10 on a 0-10 pain scale. He has no allergies, and his only daily medication is Pepcid for acid reflux. They have administered oxygen at 3 liters via nasal canula, 4 baby aspirin, and one nitroglycerin. He has an intravenous with normal saline running at 100 cc per hour. His pain is now 6.

As you begin your assessment, you find his blood pressure is now 130/80, pulse 80, respiration 24, and oxygen saturation is 100%. His EKG shows ST changes, which are indicative of ischemia. He is still complaining of chest pain, so the emergency room physician asks you to administer another sublingual nitroglycerin. Two minutes after you have administered the nitroglycerin, he tells you that he feels very lightheaded, and is more diaphoretic. When you recheck his blood pressure it is now 90/40.

You quickly put his head down, increase his IV rate, and still no improvement. His blood pressure is even lower now. He is barely responsive at this time. His girlfriend arrives, and frantically comes into the room. The first thing she says when she comes into the room is *"Honey, did you tell them you took Viagra last night?"*

Everyone in the room feels sick to their stomach. No he didn't tell us, but we didn't ask either. We all know that medication used for erectile dysfunction such as Viagra, Levitra and Cialis can cause life threatening hypotension when combined with nitroglycerin if. These mediations cause the muscles that control the size of blood vessels to relax. When these muscles relax, the vessels enlarge in diameter, and as a result, the blood pressure drops. When Viagra and nitrates are taken together, the effects are greater than when either one is used alone. There may be a marked relaxation of the muscles that control the vessels with a great drop in blood pressure. A drastic drop in blood pressure is detrimental to patients who have angina, a condition in which a higher blood pressure is necessary to supply the heart with blood. Lowering the blood pressure decreases the flow of blood to the heart and can precipitate a heart attack.

Why did this happen? The patient may not have realized that he needed to tell someone he was taking it. He may have been too embarrassed to tell anyone. He doesn't take it every day, only occasionally. He was asked what medications he takes on a daily basis. The EMT didn't ask before administration of his first nitroglycerin. The emergency nurse and doctor didn't ask either. It can be a very embarrassing question to ask. In our emergency department we now have little signs above the patients head that say "ASK AWAY" as a reminder to us to ask this question.

What are the legal implications of this case? If you are reviewing a case in which a patient has had a bad outcome after receiving Nitroglycerin, look back to see if he has ever been prescribed a medication for erectile dysfunction. Check to see if his prescribing doctor did proper teaching. Did he explain the reasons he needs to tell a health care professional that he was taking Viagra, if he is goes to the hospital with chest pain? Where did he get this medication filled? Are there warnings on the bottle and on the patient information sheet? Was this question asked before administering nitroglycerin? It is not safe to give nitroglycerin if a male has taken Viagra, Levitra or Cialis within the past 24 – 48 hours. Any health professional who has been involved in a case like this, will never forget it. So before you give nitroglycerin, **ASK AWAY.**

Medical-Legal Interface

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