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Stark Law Updates

### REVISIONS TO STARK REGULATIONS

The Center for Medicare and Medicaid Services has recently issued revisions to the Stark Regulations that tighten the prohibition on physician referrals and the anti-markup rules. How these rules impact your medical practice? You are listening to ReachMD XM160, The Channel for Medical Professionals. Welcome to the Business of Medicine. I am Dr. Larry Kaskel, your host, and my guest today is Attorney Neal Goldstein, partner with the law firm Seyfarth Shaw and we are going to discuss the practical impact these changes may have on one's medical practice.

**DR. LARRY KASKEL:**

Mr. Goldstein, welcome to the show.

**MR. NEAL GOLDSTEIN:**

Thank you Larry, it is good to be here.

**DR. LARRY KASKEL:**

Neal, can you tell me exactly what the anti-markup rules are?

**MR. NEAL GOLDSTEIN:**

Sure, it's a rule that is contained in the Medicare statute and it relates to the physician fee schedule and what the physicians can bill for diagnostic tests and the concept is that if a physician purchases a diagnostic testing, what we mean by diagnostic test is it could be an MRI, it could be a pathology lab. If that is purchased then you cannot bill it to Medicare at a profit, it is kind of putting it in its most simplest form and so what has caused a lot of confusion over the years is when is a physician deemed to be purchasing the test and in particular there is language in the statute and in the rules, which indicate that if you have these diagnostic tests that are done within your medical practice, it still could be deemed that you are "purchasing these tests" and so what these anti-markup rules are aiming to do is to address the situation of when it is deemed that you are purchasing the test and when it is not deemed that you are purchasing the test. When you are deemed to purchase the test that is when the anti-markup rules apply.

**DR. LARRY KASKEL:**

To translate that from legalese in to layman's language, for example, if I do own an MRI machine what can I and can I not do with Medicare patients?

**MR. NEAL GOLDSTEIN:**

If you own an MRI machine and if you have not satisfied these new rules you cannot bill Medicare for either the technical components or the professional component at an amount greater than your actual out-of-pocket cost for the radiologist, okay?

**DR. LARRY KASKEL:**

Okay.

**MR. NEAL GOLDSTEIN:**

So, what that means if you really take it to its ultimate logical conclusion, what that means is that you have to bill Medicare at a loss because the only thing that you would be able to bill them for would be what you are paying to radiologist to interpret the test.

**DR. LARRY KASKEL:**

What about the component, the technical component that just pays for the actual test itself, not the interpretation?

**MR. NEAL GOLDSTEIN:**

Because of a quote in the statute and in the rules, they do not deem the technical component really to be separate from the radiologist. In other words, they look at the term that they use is outside supplier. Whatever you pay an outside supplier, you have to bill Medicare for that cost. So, if were to buy that test from a free-standing imaging center and it cost you, say you know \$800 for both the professional and the technical, you could only bill Medicare and I am kind of simplifying it, but you can only bill Medicare, that \$800. If you have that imaging in-house, because of the quote in the rules they treat the radiologist as the outside supplier. So, you would only be able to bill basically what you pay the radiologist for both the professional and the technical.

**DR. LARRY KASKEL:**

So, it sounds like they are trying to prevent obviously doctors from ordering unnecessary tests and marking it up and passing through some costs to Medicare. So, has it been enforced yet?

**MR. NEAL GOLDSTEIN:**

The rules going, they were published on October 30, and the final rules they are going to be published in the Federal Register, I think some time in mid-November or November 17, or 19. They are going to be effective, January 1, 2009. There are certain components in the markup that already are in place. Whether or not they are enforcing those aspects, I would say they are because there has been some litigation on it. So, they will be enforcing it and I would suggest that they are going to ramp up their enforcement now that they have come up with the final rules that are going into effect on January 1.

**DR. LARRY KASKEL:**

So, have you been advising your clients to do something different? How is this going to play out with physicians in private practice? How about an example, a real life example?

**MR. NEAL GOLDSTEIN:**

Well, before I go in to the example, I have to tell you what the final rule say. What I have been telling you thus far is sort of the history of it and the concept and, you know, the legalese admittedly, but now I have to tell you what the final rules are saying and what the final rules are saying is that if you are a physician and you have diagnostic testing in your practice and so will use pathology as an example, you know clinical pathology, laboratory and we will use MRI as an example. If you have that, you cannot markup unless you meet 1 of 2 tests. So, they give you literally, an alternative 1 and an alternative two and I am only going to talk about MRI because it is the easiest example to give you right now. So, to satisfy alternative 1, in order to continue to have MRI and to bill at a markup, you have to, the radiologist, who is both performing the test and is supervising the test has to work at least 75% of his professional services have to be provided for that medical practice. That is alternative 1 and we will talk about that in a minute. Alternative 2 is an option that is not really practical and does not really want a lot of analysis and in my opinion seen as more or less said as much in the commentary to the regulation when they tried to address certain questions people had when alternative 2 was proposed. They basically answered in the final rules by saying, okay, may be that is an ambiguity in alternative 2. We are not going to address it here because we gave you alternative 1. They view alternative 1 as a very physician-friendly kind of alternative. Real quickly what alternative 2 says is that it goes more to the site of service and it basically says that the only time that you could markup is when the test is done in the office of the physician, who ordered the test and I won't go in to too much detail about that but if you think about a physician practice that has multiple offices, but may be MRI in only one of those offices, practically it isn't going to work and I think CMS acknowledges it. So, everybody in my opinion has to work with an alternative 1.

**DR. LARRY KASKEL:**

If you have just joined us, you are listening to the Business of Medicine on ReachMD XM160, the Channel for Medical Professionals. I am Dr. Larry Kaskel, your host. I am talking today with attorney Neal Goldstein, partner with the law firm Seyfarth Shaw. We are talking about the revisions to Stark regulations, which tightened the anti-markup rules and have new prohibitions on physician referrals.

Neal, so tell me how it's going to play out in private practice? Who is going to really get hurt the most?

**MR. NEAL GOLDSTEIN:**

Well, the people that would get hurt the most are the ones who are going to dismiss it and you definitely hear that from people that it doesn't make sense. We are not going to pay homage to it.

**DR. LARRY KASKEL:**

So, they are going to blow it off until they get caught.

**MR. NEAL GOLDSTEIN:**

Exactly. So, it is kind of with those people. So, it's going to hurt, in my opinion, smaller practices that want to have ancillary services like lab and like MRI because they don't have the kind of value to be able to afford to have a full time pathologist and/or a full time radiologist. The larger practices will and so, you know, they will have the volume so they will be able to afford it.

**DR. LARRY KASKEL:**

So, if I am a small practice and I have my own lab and I have Medicare patients, are you saying that I can no longer use my lab or I cannot charge a profit and I will just get what Medicare pays me. But, that hasn't changed because they are already just paying what they are paying.

**MR. NEAL GOLDSTEIN:**

Well, but they are paying the fee schedule amount, okay. Under anti-markup, you would actually have to charge them probably well below what the fee schedule amount is, and in fact you would have to bill Medicare at a direct loss for every lab that you do and I am talking mainly anatomic pathology kind of lab. I will have to look a little deeper in to it. I am not sure about just general labs for like blood draws and things like that, but definitely with anatomic pathology. So, the practical effect is, if you are a urology practice, lets say, and you have the kind of pathology lab that does not meet within the anti-markup rules, you are not going to bill Medicare. You are not going to do Medicare because it is going to be cost prohibitive because you will have to do it at a loss. So, you will only be able to do with a private practitioner.

**DR. LARRY KASKEL:**

So, historically, when government tries to close loopholes and improve things, they usually make things worse. So, what do you see as the doctor's response and how this is going to actually worsen the problem and not really help anything?

**MR. NEAL GOLDSTEIN:**

Well, I kind of take a different view of it. When I read it, I actually was kind of thankful that they came out with alternative 1 because it was very straight forward, cut and dry and it actually had some logic to it, may be logic that people would disagree with, but at least it was consistent with what Medicare policy is and what their policy is, they are saying, look if we are going to let you physicians profit off of passive activities, okay, and passive activities mean referral to a "designated health service" like MRI, like pathology, etc. If we are going to allow you to do that there has to be something in it for the patients and it also has to respect the Medicare program. The language that they use is they can't abuse the program, they can't abuse the patient, what they are really saying is something different. You have got to respect the program and it has got there is something beneficial for the patient. So, in this instance, what they are saying here is that we don't want you to take your, and we will use imaging as an example. We do not want 25 different radiologist reading your MRIs, that is not good quality because you know different radiologists have different training, different expertise. The more uniform that you could make this, the better quality that it is going to be and what we would like even better, Medicare speaking now, is rather than you having some kind of a tenuous relationship, you know an independent contractor arrangement, where all you do is send labs out or send

MRIs out and you get a report coming back. We want it to be a strong relationship and that is where the 75% comes in. If you have a pathologist or radiologist who is doing 75% of his work for a medical practice, he is really part of that medical practice and being part of that medical practice actually means collaboration, you know, clinical protocol, things like that, that will benefit the patient and ultimately will benefit the Medicare program because it is a more efficient and a more effective way of delivering these kind of services. So, now I am giving you the philosophical bend of it. I am going to tell you the business side of why personally I think it is a good thing for the large group practices and what that is that if you have a radiologist who is your exclusive radiologist or your exclusive pathologist, in addition to being able to control quality, it is also going to be more profitable for you because it is going to cost you less to bring something in-house versus to out-source it, at least in the healthcare industry. So, personally, in my opinion and I tend to represent larger group practices, I kind of breathe the sigh of relief, and I was able to say them, I have been kind of pushing you in that direction anyway because it makes good sense.

**DR. LARRY KASKEL:**

Why is Pete Stark so angry? Did he not get in to medical school?

**MR. NEAL GOLDSTEIN:**

You know, there was a story that Pete Stark used to sell insurance to doctors and they used to make him sit in the waiting room for 2 to 3 hours and because of that he wanted to get even with them. The truth is that Pete Stark, before he became a congressman from California, was a banker so I do not think that story is true. The funny thing is that Pete Stark himself, he does get involved in healthcare issues. He is on the health subcommittee of the House segment for Ways and Means Committee, but in terms of the Stark statute, you know his main involvement was back in 1989 when it was enacted. He does <\_\_\_\_> regulation themselves are issued by CMS, so he does not or should not I do not think have any direct involvement. So, basically, his name is attached to it. He has gotten a lot of notoriety for it, but he is not really the driving force behind it. The driving force behind it is whoever is the administrator of CMS and who ever happens to be in that particular division that promulgates this regulation.

**DR. LARRY KASKEL:**

Well, you mentioned administrator. We have now have a chief administrator, President-elect Obama. How do you think his administration will have, what do you think will be any effect on Stark Law or will just continue as it is?

**MR. NEAL GOLDSTEIN:**

I think it will change and the reason it will change is because with a new presidential administration, these agencies themselves, typically, the heads of these administrations change. So, I think that you are going to see some change. What that change is going to be is any body's guess and there is sort of this preconceived notion that a democrat is going on a socialized medicine so that is not going to be good for physicians and so it is not going to be good for physicians. You know, you could debate that one way or another the thing I can tell you with certainty is that it is uncertain, it is unknown, and why can I say that? If you look at the 8 years that George Bush has been in office starting from January 2001 to January 2009, so he is a republican and you would think that republic administration would be more friendly to physicians. I will tell you unequivocally that these 8 years have been, if you look at the regulation, very unfriendly to physicians who want to be on ancillary services. So, you would think with the Bush administration it would be contrary? It isn't. Some of the regulations and especially the regulations that have come out in the last couple of years, it is almost like they have physicians in their crossier. I don't think that has anything to do with George Bush, and I just doubt that President-elect Obama is going to have that much of an impact on that philosophical bend.

**DR. LARRY KASKEL:**

Neal Goldstein, thank you very much. It was a pleasure talking with you today.

**MR. NEAL GOLDSTEIN:**

Thank you.

**DR. LARRY KASKEL:**

My guest was Neal Goldstein, attorney and partner with a law firm Seyfarth Shaw, and we were discussing revisions to Stark regulations, which now tighten anti-markup rules and new prohibitions on physician referrals. I am Dr. Larry Kaskel and you have been listening to the Business of Medicine on ReachMD XM160, The Channel for Medical Professionals. Please visit our website at [reachmd.com](https://reachmd.com), which features our entire library through on-demand podcasts or you can call us toll-free with comments or suggestions at (888-MD XM160) and thank you for listening.

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