

2006

Transcribed Speech of Joan Polacheck

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Recommended Citation

Joan Polacheck *Transcribed Speech of Joan Polacheck*, 15 *Annals Health L.* 379 (2006).
Available at: <http://lawcommons.luc.edu/annals/vol15/iss2/14>

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Transcribed Speech of Joan Polacheck

MS. POLACHECK: I was very glad to hear this morning in Dr. Brennan's talk that maybe the fraud and abuse laws do not really cause a lot of barriers to what health care providers want to accomplish, but I've got to say, I certainly spend a lot of sleepless nights – and I have a feeling a lot of you out here do as well – worrying about whether my clients that I've given what I think is very reasonable and maybe conservative advice to are going to be the ones that get caught and meshed in some zealous prosecutor's web in deciding that whatever they did was evil. [U]sually, those evils that the fraud and abuse laws are aimed at are very related to our overall topic here of provider responses to cost containment. [C]ertainly, this is nothing new. Back when there was cost-based reimbursement, as I remember it, there were a lot of creative ways to gain the system back because there was no cost containment. There was just a lot of creativity out there. Obviously, now we have more of a fixed pie with more perspective payment and therefore, the fraud and abuse laws are more aimed at everybody trying to either increase the pie artificially or increase their slice of the pie in some manner that is contrary to the best interest of patients or the best interest of the federal health care programs.

Of course, the countervailing concerns are that the fraud and abuse laws raise barriers to more creative and cost effective quality-oriented dividing of the health care reimbursement pie. I know John Blum's slides this morning showed the cost benefit analysis and how maybe the cost of regulations is more than the benefits. On the fraud and abuse side, however, I have not seen a lot of data on that; but certainly, if you look at the government's data, they are always touting, [for example, that they] got \$1.5 billion last year from health care providers and [that they] saved the world and made the world a better place for the taxpayers and the patients. [I]f you look at the fiscal year 2004 Department of Justice OIG Health Care Fraud and Abuse Control Program report, again, it describes, starting with the highest dollar numbers and down the road, how much money they have recovered from various health care providers based on fraud and abuse issues.

I am going to [quickly] go through which fraud and abuse laws we are talking about, because this is an audience that already is obviously familiar with all of these issues. Obviously, the Anti-Kickback Law addresses payments between referral sources, [for example], between doctors and hospitals, [and between] people who want business and people who are in a

position to give business that would increase patient volume, or cause someone to choose one provider or another, or cherry pick. [T]hose are the three big factors that I will get to in the case study that I am going to discuss, to get through this tension between health care fraud and quality, which is the gainsharing area.

Stark Law addresses a lot of the same issue as the Anti-Kickback Law, but puts that emphasis on the services deemed to be most vulnerable to over-utilization or other abusive practices. [O]f course, the problem with the Stark Law is that it is completely black and white. With the Anti-Kickback Law, you look at intent, you look at facts and circumstances, you do not have to be in a safe harbor, and you can feel much more comfortable being creative. I, personally, feel very uncomfortable whenever I am dealing with the Stark Law – don't worry clients. But you cannot act as smart with the Stark Law. It does not matter if you have a good reason for making a payment, it does not matter if you have all the facts and you weigh those facts on [both sides]. [I]t is black and white. If the payment doesn't fit into one of the pigeonholed exceptions, then you are out of the box.

The next two of the "Big Four" health care fraud and abuse laws are the False Claims Law and the Civil Monetary Penalties Laws. [Regarding] the False Claims Law, I think just submitting false claims is not that big a deal in terms of some of these bigger issues. But I think the issue with the False Claims Law is that every violation of every law – in particular, the Anti-Kickback Law and the Stark Law these days – is reconstructed as a False Claims Law violation, so that you can get into the *qui tam* statute and have whistleblowers bringing these actions. [T]he Civil Monetary Penalties law addresses incentives to withhold or reduce care. [O]f course, the problem with the CMP law is that the incentive-to-reduce-care piece of it is not an incentive to reduce care – medically necessary care – but basically any care regardless of whether it's medically necessary or focused on a particular patient.

[W]hat provider responses to cost containment would implicate these laws? [A]re these laws an effective means to ensure quality despite cost containment? [D]o these laws impede cost quality initiatives, or are they really necessary because people are going to do bad things? [W]hen a provider is faced with reduced cost, is the provider going to say, "Well, let me think of a good way to reduce my cost while maintaining quality and maintaining access and all of that," or do we not trust the providers and are they going to just do these bad things, [like] have bad referral incentives, over-utilization, [and] overpayment?

[T]he classic case study of an area of the law where you see this tension between being creative in this cost, quality, access area and the fraud and

abuse laws is in gainsharing and the different responses we have seen, particularly recently, to gainsharing initiatives. As most of you probably know, there were a number of advisory opinions earlier this year on gainsharing. I think there were six of them that made people think, "Oh, now the government is loosening up on gainsharing and maybe gainsharing will be more of a possibility." In other words, [more of a possibility of] sharing cost savings, like hospitals sharing cost savings with physicians. But if you look at those opinions, they are extremely narrow. I cannot even imagine how much it must have cost the people who got those opinions to get them and to pay the consultants to do all the analysis it took to determine how they would pay physicians to save money and yet guarantee, in a way that made the OIG happy, that there would not be anything bad happening. [S]o, the question really is: Are these practical solutions, or is this really the same old, same old, that we've still got pretty much an effective ban on gainsharing? And the [question] raised by the gainsharing issue is: Do physicians have to be paid to practice in a manner that balances cost and quality, or should they be paid because they have to work and they have to do a lot of things? In particular, primary care physicians are underpaid, so if they are going to be asked to jump through a lot of hoops to obtain cost savings and quality, why wouldn't they be paid?

[T]o get to some of the different positions on gainsharing, where it is legally, and why it really brings that tension between fraud and abuse laws and cost containment quality to a head, I think it is useful to look at the statement submitted in connection with the October 7th hearings on gainsharing that were held by the Ways and Means Subcommittee on Health. I went on the website and started looking at the different statements on there, and I thought, "These are really nice, juicy statements." If I were more clever, I would have put up the quotes, and then at the end I would have matched them up. But as they are, these statements are very instructive and they just make you throw up your hands and think, "There is no way we are ever going to solve this." There is no way we are going to get to any [point] where we can have appropriate incentives for people to share the pie in a way that doesn't expose those people sharing the pie to fraud and abuse charges.

The first one is Pete Stark, who is subtle, of course, in his statements here:

Bluntly stated, the discussion we're having today is about whether to turn back time. Yet, the potential for abuse is the same today as it was in the mid '80s, if not greater. Now, with cost reimbursement, it seems to me there was more potential for abuse. But, now, as then, beneficiaries and taxpayers are the ones who will suffer if these arrangements are unleashed. Frankly, Madam Chair, the underpinnings of today's

discussion make me think that we may be paying hospitals too much. If there are efficiencies to be gained – and I'm sure there are in some cases – Medicare should be the one to reap the benefit.

Now, that's a very interesting statement because is he saying, "Well, if hospitals have enough money to share with its agents, we must be paying hospitals too much?" The whole idea behind respective payment was to give hospitals the incentive to have that leftover margin, to reduce cost, and to maintain quality, assuming there was some external way to maintain quality. They're supposed to end up with something leftover, otherwise, PPS isn't working very well. [Mr. Stark goes on to say:] "Instead, we're here today to consider ways to foster inappropriate relationships to boost physician income. Such conflicted relationships are already far too prevalent in our health system." So that's cheerful.

Lew Morris, the OIG Chief Counsel, is a little more professorial about it and basically talks about the very same factors that you see listed in the advisory opinions relating to gainsharing about what the OIG's concerns are and why the OIG makes providers jump through so many hoops in order to do gainsharing. I won't read this all but it [deals with] cherry-picking healthier patients, arrangements that allow for a physician to continue for an extended period of time to reap the benefits. Basically, the kinds of things that are all knocked down if you look at the actual advisory opinions, which say things like, "You can only have your gainsharing program for one year." So those kinds of things really make an effective gainsharing [program] and an effective long-term partnership of saving costs very difficult.

[T]his [next excerpt] is from Joanne Goodroe. She is the consultant whose company worked on the various gainsharing arrangements that were proved by the OIG. [S]he says, "Gainsharing is simply physicians assuring that patients have access to all needed technology in order to deliver the best quality care while eliminating waste in the system. It's basically the cure for everything." [I]nterestingly, she is [referring to] cost, quality, access, which were the three factors that were raised earlier, hitting the right tone here in saying that [gainsharing] is the cure for everything that ails our health care system.

But then we go back to the other side again. I thought this was interesting because this person, Martin Emerson, CEO of American Medical Systems, is representing AdvaMed, which is a trade association for large device companies. He is taking a negative view of gainsharing, as I suppose many device companies with cutting-edge devices would, saying, "Under a gainsharing program, the balance between patient care and cost-cutting will be skewed. Patient access to the best care could be

compromised and virtually insurmountable hurdles for adoption of beneficial new technologies could be created.”

So he is worried that if they have a great new invention that is very expensive, hospitals are very, very reluctant, obviously, to invest in that new technology because there is no payment for it. [I]n particular, the one thing that makes the hospitals sometimes invest in that expensive new technology is that the physicians push them to do it. Now, if the physicians are getting paid to save money, [then] maybe you won't have the physicians pushing them to do that anymore.

On the other hand, I have a client who thought gainsharing would help them. They thought it would help them do joint ventures with physicians without as many problems. I had to tell them, unfortunately, that was not going to help them any. But a lot of technology companies are doing joint ventures, like equipment joint ventures with physicians and then leasing the equipment to a hospital, and some of those things do lend themselves to gainsharing arrangements. But it is true that most new technology makers are going to be very wary.

The next [excerpt goes] back to the AHA – I don't know where I got it – the AHA is working on a report, there's a task force doing a report on gainsharing, and I have a copy, and I couldn't figure out where I got it. It just suddenly was in my folder on the October 21st draft of a task force report and it is very similar to Stuart Fine's testimony that is really a systematic discussion by the AHA of what the AHA would like to see in approved gainsharing. I think one problem with the AHA's proposed argument is that it is compelling but it's not detailed enough. He says:

Currently, federal laws are focused on prohibiting or limiting interactions between hospitals and physicians that might have monetary value to either party. While the intent is honorable to avoid conflicts of interest, the effect is to impede the ability of hospitals and physicians to work together using incentives to improve quality, patient safety, and community access to services. The current federal focus on sharing cost savings gives rise to a fear among beneficiaries and consumers that such efficiency-only incentives would result in things like curtailed care and slower adoption of new technologies and treatments. We believe Congress should modernize the current concept of gainsharing and focus on the broader goal of fostering hospital-physician arrangements that provide incentives for care improvement.

It is important to [note] that this is not just cost containment, [but] it is actually improving quality and access. Then they do throw in at the end, and I feel bad because I'm being selective on how I'm quoting, but the end [statement indicates that], just in case people might think gainsharing is

enough, let's make sure you still can't have specialty hospitals with physician investment, because it says, "At the same time, we also urge that Congress not view action in this area to be a substitute for a permanent ban on the use of the whole hospital exception under the Ethics in Patient Care Referrals Act by physician-owned limited-service hospitals." I thought it was a little amusing that it had to be stuck in there at the end, in front of Congress.

The next one is interesting. It's the CEO of American Association of People With Disabilities. The concern here, of course, is that in a gainsharing arrangement, a physician is going to make sure, as much as possible, that any patient of that physician who has some kind of chronic condition or disability isn't the one that goes through the system where the physician is being measured based on cost. So, obviously, whatever system would be adopted would have to address the issue that you can't save cost just by denying access to the disabled.

[T]hen, finally, this [one] is the physician response and I think this piece was very interesting because this Jeffrey Rich, Chairman of the Society For Thoracic Surgery Task Force on Pay For Performance and Chair of the Board of Directors of the Virginia Cardiac Surgery Quality Initiative, goes on about how this particular group has been working on these issues for a long time. It was very impressive that the physicians have put a lot of energy into this issue. I have to apologize to this person for taking the last paragraph out of context somewhat, but [it says]:

In conclusion, the STS and its regional collaborations such as the VCSQI have been involved in QI for the past 15 years. These improvements have occurred in an era of declining reimbursements and without incentive payments primarily because we feel this is our professional responsibility. I personally feel that the greatest privilege society has given us, as physicians, is the ability to care for patients. But on behalf of all physicians, as perhaps the primary drivers of quality improvement, and hence health care savings, I must ask a central question about gainsharing. Why should physicians, who drive much of the gain, be the only group excluded from the sharing?

Now, I can see somebody from the OIG's Office or the Department of Justice saying, "See, they are saying we want a piece of this pie, we want a piece of the technical portion, not because we worked to create the savings, but we're the ones that referred to that technical portion, we are the ones that enabled the hospital to earn that technical portion, [and] we want our share." So I think something like this definitely can be taken out of context and, again, illustrates this big tension, to which I don't have any answer, between the fraud and abuse laws, which keep us up at night, and the thing

we all have to do, which is move toward trying to [implement] initiatives that lower cost and maintain quality and access.

I just have one more slide on just another set of issues that I don't have time to get to, but it is a set of issues I've dealt with a lot that, again, raises tension between cost savings in a way that I think is appropriate and the fraud and abuse laws, which is just pricing issues. I think the discount safe harbor under the Anti-Kickback Law was drafted in a cost reimbursement era and has imbedded in it a lot of suspicion around creative pricing arrangements under the assumption that creative pricing means that what really is being done here is that the buyer and seller are trying to gain the system and get more money out of Medicare, where really under PPS, a lot of these creative pricing mechanisms are simply trying to get to a win-win situation where both the buyer and the seller can get to a point where they're comfortable. [O]f course, hospitals under PPS don't want to buy a big piece of capital equipment because they are only going to get paid for it if they use it. So a lot of manufacturers these days, of course, are putting together bundled pricing arrangements where there's no separate payment for the capital equipment – it's not really free, but it's not separately paid for – and the payment is made on a per-click or per-service or per-case basis or is actual payment for the disposables, whereas the hospital buys a package of the disposables and uses the equipment, the payment is made. There's still a lot of uncertainty about those arrangements under the fraud and abuse laws and if you read some of the government briefs in the Ross Abbott settlement, it's very scary to those of us who give advice in this area. I think this is another area where definitely some loosening up by the government is needed so we can have more creative pricing in the PPS area.

Thanks very much.