

2007

## Transcribed Speech of Dr. Kenneth Kizer

Kenneth Kizer  
*Medsper Systems Corporation*

Follow this and additional works at: <http://lawcommons.luc.edu/annals>



Part of the [Health Law and Policy Commons](#)

---

### Recommended Citation

Kenneth Kizer *Transcribed Speech of Dr. Kenneth Kizer*, 16 *Annals Health L.* 323 (2007).  
Available at: <http://lawcommons.luc.edu/annals/vol16/iss2/8>

This Colloquium is brought to you for free and open access by LAW eCommons. It has been accepted for inclusion in *Annals of Health Law* by an authorized administrator of LAW eCommons. For more information, please contact [law-library@luc.edu](mailto:law-library@luc.edu).

## Transcribed Speech of Dr. Kenneth Kizer

DR. KIZER: It's a pleasure to be here. I'm honored to be included among the faculty who certainly are going to be addressing a very complicated and difficult issue, and one that is emerging and perhaps may, in some cases, end up being a showstopper in some of the other things that are being pushed hard in the public agenda, if we don't come up with some solutions to some of these issues that are longstanding issues. But there's a new sense of urgency, I think, to address the issue, because of a variety of forces that are coming together to push the electronic health records and all of the things attendant with that.

Now, there are a number of ways we could have sliced the day up. One of these could have been to spend a lot of time talking about HIPAA—what it does and doesn't do, and where it has shortcomings, et cetera. Or there are a variety of data issues that we could talk about. However, I thought that as the first speaker, I would spend a fair amount of time providing some context for what's happening in health care to set the stage for some of these other discussions, and understand the importance of moving to the electronic health record. I plan to discuss the context in which this is occurring and some of the forces that are driving the healthcare agenda that make secondary use of health data so important and really are creating the market for this data. I want to say a few things about what some of the benefits are of digitizing personal health records.

Let's make sure we're clear about the secondary uses. Priority of privacy, confidentiality, security, and work incentive are not the prominent issues but, again, there is a new sense of urgency because of the forces that are driving the electronic health record. I'd like to end with the suggestion of the need to establish a national framework for how we may address this whole problem of secondary use of the health data.

Let's talk about the state of American health care for a few minutes and really the paradox of American health care. I hope that this is a review, and that I'm not going to say anything that you don't know. But I think it's important to reinforce the context in which we find ourselves and why health records are so important and why the market is so great for bi-products, in and of themselves. Certainly there's no question that in the United States we have some of the best-trained practitioners—physicians, nurses, pharmacists, and other healthcare practitioners—available in the world.

The diffusion of state-of-the-art diagnostic and treatment technology through our communities is really unparalleled in the world. Also important is the biomedical research program that is present at NIH, and others as well—the scientific engine that’s driving so much of the good things that are happening in health care around the world. There’s no question that for some individuals, they receive absolutely excellent care—second to none anywhere in the world, here in the United States. Those are the good things. I think those are the things that people will focus on, and even today you’ll find some elected officials talking about America having the best healthcare officials in the world. These are the things that generally are heard. But I think that it is increasingly obvious to all of us that, in fact, we don’t have the best healthcare system in the world. We have a healthcare system that is plagued with all kinds of problems.

Indeed, the first problem is that we don’t have a system. We have a lot of services that are sometimes united in some sort of a dysfunctional manner. Occasionally, it may work well for patients, but too often they’re very confusing for both practitioners and patients alike. We have a large number of our population, which does not have guaranteed access to health care simply because they don’t have insurance. This country is also experiencing a rapidly rising incidence of chronic disease, especially as it relates to the epidemics of obesity and, in turn, diabetes. There are a number of different types of healthcare personnel—nurses, pharmacists, x-ray technicians, and others—that are in critical shortage and that are not distributed to those in need in the population.

There’s no question that there are widespread quality and safety problems and I want to delve into this in a little bit more detail here. A few years ago I was a member of the Institute of Medicine’s National Roundtable on Health Care Quality. We published our report in a large form, as is typical in medicine, but a shorter version also appeared in the *Journal of the American Medical Association*. Not that the Roundtable gave birth to the idea of improving quality, which has since been published in the set of reports and the ultimate letter reports, but 1998 will certainly go down as a watershed year as far as quality of health care is considered in the United States.

The Roundtable published a report, the *President’s Advisory Commission on Consumer Protection*, on the quality of the healthcare industry. There also were investigations that were run, and another analysis of qualitative PR was published in the fourth quarter of the magazine. Unfortunately, all of these publications came to the same conclusion that is stated here—that there are very serious and systemic problems in the quality of health care in the United States that are unrelated to form of payment or method of delivery, and that there are wide variations from what the evidence says

should be provided and, indeed, more recent studies. They're basically talking about an agency that has even odds or an even chance of getting you the care that you should have, so it's a little bit better than fifty-five percent, based on the evidence.

Those are certainly not statistics that are so weak [that] they express a problem. We certainly know [in] seeing newspapers and others that have highlighted in recent years the problem of medical errors, and depending on which data you look at, emergency medicine. Some are up to 100,000 deaths a year, and the health grades put that number at about twice [100,000]. Their methodology is one that I don't frequently agree with, but I think that a number of papers were recently published reinforcing the problem of health care associated with infections. There are estimated to be more than two million healthcare-associated infections a year, causing 90,000 deaths. The leading cause of that is simply everyone failing to wash their hands. This is an example where the public policymakers simply don't get it—that starting at about two or three years of age we teach our children about the necessity of hand hygiene. And certainly as one matures, by the time one gets to nursing school or medical school or whatnot, then this should be deeply engrained in your head. We have 50,000 deaths a year. In particular, doctors and nurses are displays, if you will, to wash your hands. That's certainly how the public perception of this is and I simply don't get it and it truly is an unacceptable statistic.

Yet, depending on which numbers you use, medical errors are probably the third leading cause of death in the United States. This is a somewhat sobering thought if you're looking at going into the hospital for anything. Everyday more than 250 people die because of preventable medical errors. Again, I just wanted to underscore the issues here and to provide some of the context in which the trial of electronic medical records is occurring and to quote [the] Institute of Medicine, “we don't just have a gap between the care of what should be delivered and what's being delivered, but we have this huge chasm.” I've said a few other things about the paradox of American health care.

There's no question that we love technology. There is at the moment this uncontrolled proliferation of technology compared with the form of cost benefit analysis being done, [and] widespread waste and inefficiency, including fraud. Most people would estimate that somewhere around thirty percent of all the dollars that are spent are simply wasted. To quote Paul O'Neil, former Secretary of the Treasury, he says it's fifty percent. He's got the numbers probably a little bit high but it's somewhere in that range of twenty-five, maybe fifty percent. It is certainly more than enough dollars to pay for all of those who don't have health insurance, if we could just get a hold of some of this waste and inefficiency in actual dollars. And of

course to cap it all off, we probably have by any measure the most successful [nursing] in the world. Our per capita expenditures vastly exceed anybody else in the world. Any other way you slice it, it is more than any other country's spending, and I just want to say two numbers here that I think help set the context of all of this.

It was in 2003 that American healthcare expenditures reached \$1.7 trillion. It took us 227 years to do that. By 2013, if not before then, we will have doubled that number to \$3.4 trillion. So it took us over 225 years to get to the first and it's going to take us less than a decade to be more than double that. Most likely we will get [to] that before 2013 with the current rate that expenditures are rising, at which point then health care's benefits will be about 18.5 percent of the [GDP]. We're going to blow through eighteen percent and twenty percent and twenty-two percent and, frankly, there's very little that can be done to stop this in the short-term.

Just to take a moment, why are the healthcare costs rising so much in the United States? Here [are] the top ten causes, and they're not necessarily priority-ranked at this point; you might rank them differently. But as you go down this list, the question[s] one might ask oneself, is which of these things can be controlled in the short-term? Which of these things could we realistically have some sense that we could actually slow down the rate of growth in the next five years, or maybe the next seven or eight or ten years? Population growth, especially the growth of the elderly. That is going to continue for quite some time and of course with that, the elderly use more healthcare services. Not surprisingly, they are the number one driver of increasing healthcare costs. Increased chronic care needs. Again, many of the advantages or the benefits of the scientific discoveries that are being made [are] that people who formerly died are now being kept alive. Chronic disease is expensive.

Uncontrolled proliferation of technology. This is America and it's a cultural thing. We love our technology and it's not likely that any time in the short-term [we will slow it down]. Direct consumer marketing. What started off as a few million dollars-a-year enterprise, and all of a sudden we're looking at pharmaceutical companies [with] about 5.5 to \$6 billion a year advertising effort. Why? Because it works. Those ads are very convincing. People come in, and they want those products that they see advertised on TV. But the state of the healthcare service mandates it both at the state level and the federal level. This may be a good thing. Let me give you an example. Years ago when I was Director of Health for the state of California, many of the insurance companies didn't cover reconstructive surgery after mastectomy and we didn't feel at the administration that that was a good thing, and so [we] pushed through legislation to make sure that that would be covered. The fact is, it's a good thing. There are a myriad of

other examples like this, but there's no question that that also drives healthcare costs up because those things are now mandatorily covered. Consolidation of healthcare providers. Hospitals are combining, doctor groups are combining, the health plans are combining, all of which is to negotiate better prices. Again, this is a significant factor in driving healthcare costs up. Rising liability insurance. And it's a crisis. About twenty-two states still have no reliable solution apparent certainly in the short-term. Fundamentally, this is a disconnect we're trying to solve—a very technical, sensitive issue with the criminal justice approach and it is a fundamental mismatch of behavior to fundamentally rethink their role in regards to liability insurance, but [it is] not likely that anything is going to happen in the short term there.

We are what has been characterized as a consumptive society. Basically, if a little bit of home care is good, then more must be better, and even more must be even better and that's the mindset of most people. And the idea that you [don't need] these X-rays, you [don't need] antibiotics or anything like that, is something that most people don't want to hear. We're talking about waste and systemic inefficiencies. It's just that waste is built into the system. It involves a clear evaluation of best evidence, poor quality, no question of that, and [we] know that it's [due] in particular to rising healthcare expenditures. That is probably the one thing that can be addressed in the short-term. One of the reasons why so much attention is being focused on quality improvement is that there's some likelihood that it might be achievable in a shorter time frame than some of these other things. Certainly over the next decade, one of the forces that is going to be driving the healthcare industry is going to be efforts to control rapidly rising costs. These efforts come in different disguises, but fundamentally that has been [around] for some time and will continue to be the major driver for healthcare reform.

[There is] increased demand for services because of the number of these other things that I just mentioned, like proliferation of new technology. We're getting into whole new areas of technology with genomics and other things where these are truly frontiers and there's lots of ethical and other issues that have to be addressed in their own right.

The demand for safer and higher quality in health care is high on the list and it's going to probably rise even higher. Certainly [a] cost shift to consumers [will] occur with consumer credit plans or some of the other boundaries we've set, [but] we are [also] in an environment to shift costs as well to employers, [who will] assume the larger burden as their costs tend to go up. Increasing demand for personalized care. It is now possible to increasingly tailor care to the needs of individuals and that would be an increasing force as we move forward again and can lead to potential. The

genomics is huge for this although there's still some resistance out there.

And also there's the growing demand of widespread adoption of information and technology. Indeed, modern health care is, without question, the most information-intense enterprise that human beings have ever engaged in. Modern health care is all about information management—whether it's drugs and side effects and interactions, radiologic findings, history, or the gathering list of other things—modern health care is all about managing information, even though we are managing much of that healthcare information the same way we did it 150 years ago. Certainly there's a movement, in a way, that's gaining considerable momentum to move us into the 21st century as far as how healthcare information is managed and finding the appropriate level of records.

Indeed, if there is one single thing one could point to [that] would have the potential to improve the safety, the quality and the efficiency of American health care more than anything else, it would be the widespread adoption and use of electronic health records. Again, modern health care is all about managing information. We do an abysmal job by and large with this. With the wider adoption of electronic health records, there's some potential to actually make some marked improvements, as has been observed, and there's certainly real world experience that one can point to where that has been a key element in the major turnaround.

The VA [Veterans Administration] is a good example of some of our larger systems where data that has been part of a larger transformation, and indeed, they are functioning at markedly improved levels than they historically did. Electronic health records are simply a critical tool. They're the enabler for some of the other major forces that are occurring in health care. And certainly in public reporting and performance, the desire [exists] for increased transparency and accountability in health care [to] provide consumers and purchasers with the information that they would like and need to make their decisions. Having electronic health records is a key underpinning for making that happen. Certainly in pay-for-performance and operationalizing data performance, electronic health records are going to be key. And the preservation of records is a requirement that can only be managed by electronic health records. Certainly with this and with the digitization of medical records, it is inherent that their use provides really impressive opportunities to research and analyze personal health care and healthcare delivery problems in ways it used to be impossible to perform. [This is] because there's vast amounts of data from disparate sources [that] are going to be available and it will be possible to link these in different ways; the opportunities here are just immense.

Just in recognizing the fact that electronic health records are not a new idea, we'll go back to the late 1960s and certainly the 1980s. This was a well-recognized idea that we needed to move in this regard and the question we asked was, why here in 2007 are we on the poise, if you will, to do something that people have been talking about for at least three decades? There are a number of reasons of why, including cost, which is probably the single most important barrier. It is the cost of these large systems. The [medical information management industry] doesn't have a great track record with the initiatives and with providers. Much of the software that has been advertised as being the solution simply does not live up to our expectations, or ended up not being a viable business case, and the provider of that technology went out of business and somebody was left with a system and basically no one to support it. Health care remains primarily a cottage industry and that involves cost issues. Providers aren't able to afford these large systems.

Most healthcare professionals aren't very well versed in IT either. This has not been our focus, although there are certainly some that delved into this. But if you look across the board at doctors and nurses, you know, this is not their forte. I'm reminded not too long ago of a presentation we were doing at a hospital in Los Angeles where most of the folks, when they [left the presentation], eventually one after the other essentially said, "I hate computers, I don't want anything to do with computers." This, you know, is the mindset of a lot of folks who are running a practice today.

Certainly when you look at the time pressures that physicians are confronted with today, trying to keep up with the new developments in their own specialty, to say nothing of health care overall, and then to go outside of their area and be confronted with something like that, it's just more than one can expect, I think, from most doctors. They're not going to go spend their weekend learning about some new software, when it's certainly not something that is likely to add to any future work or otherwise in their day-to-day practice. The lack of following standards has been a problem, but by and large, nobody's been pushing this agenda. It's something that everyone says, yeah, we should be doing this, it is a good thing, but there's no one saying, you know, thou shalt do this and thou shalt do it by this time and, if not, there will be consequences. That is a large part of what has changed in the last few years.

I'm aware that President Bush issued an executive order in April of 2004 that established the Office of the National Coordinator for Healthcare Information Technology. But the goal was set that by 2014, the majority of Americans would have or would be in healthcare systems in which electronic health records were managing their information. This is a

completely unrealistic goal in my mind, but it was good political rhetoric at the time.

I want to thank the American Health Law Information Community, which is doing a number of things to push this agenda forward. More recently, another agenda we're pushing has specified that as of four weeks from now, January 1st, 2007, all federal healthcare programs must use interoperable healthcare information technology whenever possible. That applies to CMS, VA, and a number of different programs run by the federal government.

Certainly as a member of the purchaser initiatives, most notably in the Leap Frog programs, initiatives are pushing safety as a priority, not as an efficiency or cost savings benefit, but for the sake of the priority of quality improvement, safety in electronic health records [is essential]. CMS and much of what it's doing in pushing both pay-for-performance and public reporting is moving this agenda forward. There's a larger number of other initiatives by purchasers. In just the pay-for-performance arena, there's over one hundred such initiatives underway. There's a lot of activity in this regard. It's all moving the field forward. There are state initiatives where I understand laws have been passed that are pushing this to jump forward as well; foundations like the Robert Wood Johnson and California Healthcare Foundations are pushing things along as well. There's really a confluence of forces that are moving the electronic health records into center stage where it's never federally occurred before and with that, of course, comes the digitizing of personal information.

Really the topic of today's seminar here is about secondary uses of that data. We know at the moment that there is a multi-million dollar problem, and that it hasn't already focused on selling data that's become available with those records so far for secondary uses. I'll note again just to make sure we're all on the same page here, secondary use of health data really refers to anything other than using the information for the care of the individual. There's a long list of things that I am going to highlight. Some of the potential secondary uses certainly include the research opportunities—the opportunities to analyze everything from looking at the effectiveness of different treatments and diagnostic tests, screening programs and prevention strategies—there's an array of research here, including just looking at the prognosis and the potential survival statistics associated with different conditions or different treatment. The potential is there of amalgamating a large source of data to come up with information that's been hard to quantify in the past. What's the natural history of conditions and natural history of the different environmental or social circumstances? Who are the at-risk populations? There's all kinds of queries that one could impose on these large data sets and just to go data

mining and throw out hypothesis after hypothesis just to see what comes out of them—looking at health trends, looking at what are the health population and subpopulations and where we need to target our services, where we need to refocus, how we can [achieve] access or improve access, [and] improve the satisfaction of services as provided.

We look at the cost effectiveness of the different inventions and some of our policy issues [and] what some of the performance [functions] need to do—clinical audits, whether at the individual practice level, local, regional, or national practice levels—all of the different levels. We can look at performance and different quality improvement strategies and one could add a lot of other things, but these are just some of the potential uses for this data. Indeed, that would make the case that in the present climate you could step back and look at what the state of American health care is—one of the issues we're confronted with. This is [a] very high priority. This is very important stuff. We need to be able to look at this data and do these types of studies in ways that have never been done before because we're reporting problems that are begging for solutions. It's important to keep that context in mind not only as we talk about some of the general issues of privacy and confidentiality, et cetera, [but] then within the context of saying that there's some very important and beneficial uses that can go along with this.

There are other potential uses in prior certification and accreditation of the facilities and targeting of services that we've already mentioned, and even marketing of the goods and services. It is important that the folks have the things that they should have and the services are meeting their needs. This is one place where we're starting to get into some very gray areas—marketing and its use in commercial purposes—and the slope can get pretty slippery there. With all of these potential benefits, though, we'll mention at the outset here these issues of privacy, confidentiality and security, and performance incentives—all of which have been around for a long time. I think what's different, though, is with this push for electronic health records, these are very real issues that, if they're not addressed in a forthright manner, might have some very vivid show-stoppers [hindering] the development. There are clearly some undesirable secondary uses, some of which are not that far-fetched—certainly the potential to restrict or tailor insurance coverage or benefits from persons who are in an at-risk population—and that at risk could be any number of things, whether it's familial history or laboratory results or economic preventatives, environmental exposures, certainly coverage in ways that one might argue are not normal nor fair; the restriction of employment according to one's history and different at-risk variables; and predatory marketing. This information could certainly be used to sell to populations with scare tactics and the information could be honed in and targeted to those who are most

likely to be susceptible to a given message and to selling bogus products. Certainly in selling personal data about public figures, there's a huge demand for information, and specifically the most personal information about anybody who is in the limelight. There is one example, when President Clinton had his heart surgery, and it was done under a pseudonym, but there were dozens and dozens of documented attempts of actors trying to get in there and get all the information about his care there in New York and that is to be expected.

Again, as we mentioned, these concerns aren't new. Really, the issue is simply the growing availability of data and the tools that now are making this data more accessible that are creating a certain urgency to address them that, heretofore, has not been the case. What I would advocate then to address these concerns is a need to develop a national framework for secondary use of the health data. I was pleased to see very recently that the American Medical Information Management Association put forward some expert edicts and guidelines. There are some recommendations in this regard that they're taking from some operative issues, but I think that their suggestions or their recommendations for what needs to be done are right on point for how we need to move this forward. But if we're going to have this national framework, it needs to be premised on the idea that secondary use of health data has to be conducted and managed solely through the use of open and transparent processes. We'd have to know what the rules of engagement are, who has access, who doesn't, under what circumstances, and for what purposes, et cetera.

Today there has been too much focus on who owns the data and that's really an irrelevant point. Certainly many of you will start talking about the mixing and matching of databases and the linking of different databases. That becomes irrelevant. [We need] to ask, what is really much more important is, who has access, who has use, who has control of it? Ownership doesn't really matter when those other things are considered.

Much of the discussion today has been either focused on privacy or confidentiality concerns or, at least in the research community, on what the potential benefits are. But, there hasn't been much overlap and there certainly hasn't been anywhere near a public dialogue about what are the advantages and the benefits of the public good that can come out of the secondary use and why we need it and why it is so important to make sure that researchers have access to this information at the same time that efforts are undertaken to ensure the privacy and confidentiality. That public dialogue needs to occur. Thinking back, I was in Washington during most of the time that HIPAA was being created. There was very, very, very little dialogue ever about what the benefits are of this information. There was lots of dialogue about the potential risks of the misuse of the data and why

we needed to put that legislation in place to protect you, but nowhere along the way did someone say, wait, wait, wait, there are also some good things that we need to keep in mind on it as well.

On the mundane side, we need to create a standardized taxonomy for the secondary use of health data. Taxonomy is one of those really unsexy subjects that no one can get excited about, but it's absolutely essential to moving a topic forward, especially how do you define events, how do you group them and characterize them and do we all have the same lexicon when we're talking about these different uses and we've got to know that that's something that needs to occur. There are a lot of questions that aren't answered and while these are not new issues, I think in terms of the potential uses and the questions that are going to come up in the future, frankly, we don't know what these questions are. We need to put in place a process by which those questions can be fielded and dealt with in a deliberative and thoughtful manner.

Finally, we need to make sure there's a roadmap that depicts and identifies all the different uses or potential uses of the data and how this might all unfold. [There are] a lot of questions about how we do this and how it actually would occur. I would say [that] what we need to do is to start the dialogue with some of these basic goals as part of that discussion, and to make this happen, somebody needs to own the issue. I would argue here for a federal agency or federal entity, at least, to be designated to lead the development for the [beginning] and everyone be accountable to look for it. It's not going to happen unless someone does take over the shift of it. This is, like lots of other public issues, an appropriate role for federal government to lead the effort into something that has to be widely a public/private effort. All sectors have to be involved, but the federal government should take the lead for it. The resources are going to have to be committed to engage in the discussion to have the sort of public dialogue that needs to occur [and] to build the coalitions of the different collaborations that need to occur.

Finally, I would recommend that an appropriate public/private venture also be engaged, such as National Quality Forum, which has brought representation from both the public and the private sectors, from consumers, from purchasers, from the providers, from researchers, from essentially all sectors, to develop and enforce standards and best practices for what the secondary uses are to help meter the dialogue, and to help guide some of the discussion that needs to occur. Again, unless they're specifically tasked with it and resources committed to make that happen, it is not likely that much progress will be made. But I think that if we don't do these things, we're going to be having an increasingly contentious dialogue about privacy and confidentiality that's going to be led by

anecdote. That is not the best way to make public policy, although, as often, we'll stipulate some movement in the area. But hopefully if we could take the recommendations, again, that the American regulatory management members move forward, I think would be very helpful in moving this agenda forward.