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Next Up For Washington Attorney: Regulatory Clarity For Clinical Decision Support Tools

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Diverse interest groups are creating a new Clinical Decision Support Coalition to weigh in on FDA policies for clinical decision support software.

Recently, the agency signaled plans to write guidance explaining how it will regulate medical software that converts health-related data into clinically actionable decision-making tools, such as software applications used to inform diagnosis and treatment options. FDA held a public meeting on the topic in September. (*See "FDA Outlines Path For Guidance On Clinical Decision Support Tools" – "The Gray Sheet" Sept. 19, 2011.*)

The coalition's goal "in a nutshell" is to see that clinical decision support software isn't overregulated.

Epstein Becker Green attorney Bradley Merrill Thompson is leading the coalition's efforts. (*See "Clinical Decision Support Coalition Building" – "The Gray Sheet" Nov. 7, 2011.*) Thompson, who also runs the mHealth Regulatory Coalition, recently spoke with "The Gray Sheet" about the fun and challenge of pulling together diverse stakeholders to tackle common concerns.

"The Gray Sheet": How did the idea for the new clinical decision support coalition come about?

Bradley Merrill Thompson: This has happened to us a few times. Our firm is one of the largest health care practices in the country. When an issue comes up like FDA's initiative in decision support software, we start hearing from lots of different quarters their concern about what the development is.

In this case, we started to hear from a fairly diverse set of folks – people who are in the EHR [electronic health record] business and payers and hospitals and other health care providers – concern over the direction that FDA was thinking about going in this area. It's a matter of trying to be efficient, to help a number of companies all together.

But also it's the politics of it, that a group that bands together and works to develop a consensus among a broad group has a more persuasive work product when they're done.

We started encouraging these folks to work together rather than each go individually. And because they were coming from so many different industries, there wasn't a trade association that represented them that could do it for this [whole] group because you've got folks who aren't normally working together on FDA- related issues who all have an interest in this.

EHR vendors haven't historically been regulated at all by FDA. They had no trade group that had been actively working on those issues that could also include payers and providers and traditional medical device companies and so forth.

We recommended that they all start to work together. We put together a draft of what the goals and objectives would be. And once that was together, we thought we ought to try to develop the consensus as broadly as possible. We started inviting others to participate, and it kind of snowballed from there.

TGS: What is the primary mission of the coalition?

Thompson: In a nutshell, it's simply to try to ensure that decision support software doesn't get overregulated.

There's a general understanding that some types of decision support software probably need FDA regulation. FDA has regulated certain types of decision support software for years. But I think what was heard in that September FDA hearing was a desire to re-examine the parameters of what they regulate and do away with some principles maybe that have been around for a while, like competent human intervention. The agency seemed to be drifting away from that concept as well as the concept that how the data gets entered matters.

Historically that made a big difference. If it was data automatically transferred from a medical device, they came at it from an accessory standpoint and said then the software is regulated. But they're moving away from some of those principles to a much broader set.

I don't want to pre-judge where FDA is going; obviously, they're just brainstorming at this point.

The group just wants to start brainstorming at the same time so that we can offer constructive ideas, kind of like the mHealth thing, where the agency and the industry were working in parallel. The industry was trying to be transparent throughout that. And by September, industry came up with a proposal that had a ton of input into it.

You might find the same thing going on here. FDA obviously is internally thinking about these issues. The industry will come together and will be thinking about them and will try to be transparent so that FDA and everyone else in the health community knows what we're doing. And then hopefully they converge at some point, and what comes out of it is a combination of what the industry has identified as best practice and what FDA has identified as legally and regulatorily necessary.

TGS: Is there any timeline yet?

Thompson: We're trying to move quickly with this organizational process, because our understanding is that FDA is actively working on the guidance documents. There's really no time to waste. We hope to be operational by the first week in January.

Then I've got to be realistic: These issues are really difficult. Intellectually they're really challenging. I would expect it would take us a few months to get everyone together, roll up our sleeves and try to figure out a sensible proposal to make to FDA.

"When you have a group that comes in with no [FDA] background, they challenge you to think outside the box."

Maybe the second quarter of next year might be a reasonable target for having something done. I'd love to do it sooner, and if we can, we will. But there's 30 people already signed up. We're getting consensus among a lot of different organizations. There are insurers and EHR vendors and health care providers. They come from very different perspectives. Their experiences are different, the economics are different, what they're each trying to accomplish and so forth.

Fortunately, everyone is focused on the patient. That's what you have to do in a coalition like this: get everyone to focus on what's best for the patient, and then build a model around that.

But it takes a while to really develop that when there are a lot of people from very different backgrounds around. I'm expecting it to take a little while, frankly, to meld all those together.

TGS: How do you expect your experience with the mHealth Regulatory Coalition to overlap with that of the new coalition?

Thompson: The experience with the mHealth Regulatory Coalition has been wonderful. A really neat group of people came together with very differing backgrounds again. You had telecom companies, you had handset manufacturers and chipmakers who didn't have, previous to that, any experience with FDA. Initially there was an educational period; there was a period where we were all learning what even the existing FDA rules were to use that as a foundation to make a proposal for where FDA ought to go.

But there was so much energy and excitement and frankly innovative thinking.

Thompson hopes the coalition and FDA can find a way to balance industry best practices against what is legally and regulatorily necessary.

For 25 years I've been doing medical device law. When you have a group that comes in that has no background with that, they challenge you to think outside the box, to think differently because they don't have all that baggage. So I found them pushing me in really creative directions, and that was a lot of fun for me. It was a growth opportunity for me. And I'm expecting it to be the same thing, with a lot of people outside of the traditional medical device field now all coming to grips with what these issues are. I expect it to be an opportunity for some innovative thinking.

There will be a little bit of overlap in that if you have an app on a cell phone that takes data in, runs an algorithm and then makes a recommendation, then potentially that app is clinical decision support software. That's a very small piece of the overall clinical decision support software pie, but there is that overlap.

When we get into those issues, I might even recommend for a session or two that we have a joint meeting of the two coalitions so that they can stay in sync with each other. For ethical reasons, I can't take two inconsistent positions, so if I'm counseling both, I've got to try to develop some consensus between the two.

I think there will be some overlap in members. There are four or five or six members of the mHealth Regulatory Coalition who've already said that they're interested in the second one; I imagine that there will be an overlapping set of company members as well.

TGS: How broad will the trade group outreach be for the coalition?

Thompson: The trade groups will principally mirror the sectors that are invited from an individual company standpoint. You've got the EHR vendors, and there are some trade groups that represent them; you've got payers, meaning insurers, and then the hospitals. You've got medical device folks, just the familiar folks there.

The other area, which is very wide open, is the clinical community, both patients and professionals. That's a very important group to include. When you get to decision support software, there are two components to that. There's the coding, what the software experts bring to the equation, which is how to design the software programs to do all the work that needs to be done. And then there's the intellectual clinical piece. And more often than not, those are clinical guidelines, and those clinical guidelines are developed by clinical societies.

We need to include the clinical societies because they're really the developers of the content that goes into this, and then they're the ultimate end user. They're the doctor who punches the information in and sees what kind of recommendation the computer spits back. That's obviously a big category because every clinical specialty has its own society.

TGS: You could have your hands full.

Thompson: We're not going to overdo it, but if we can get a good representative number, if we can get four or five of those folks to the table, that would be very valuable. We don't need everybody, but we need enough to feel like we get that perspective in the discussion.

TGS: What about patient groups?

Thompson: Absolutely. They're stretched so thin, sometimes it's difficult to get them engaged because there are so many different things that interest them. And some of them aren't terribly well funded, so they don't have a lot of staff to cover these various issues.

I'm going to reach out to the folks who commented [on FDA's recent mobile medical apps draft guidance] because that's a great way to connect with them to see if they're interested.

And if the mechanics end up the same way, what I do is I offer that free of charge – the nonprofits can participate without paying any dues. That's important because they don't have the extra money sitting around to participate, and I don't want that to be a barrier to their participation. The companies end up shouldering their burden through the dues structure to try to allow them to participate.

TGS: How do you expect the interests of the different industries to overlap or contradict each other when it comes to clinical decision support?

Thompson: Going into it, I'm not aware of where their interests will oppose each other. They're just interested in different segments of the software business. You've got the EHR folks who have business models that are mainly on-demand information. That's the defining characteristic of an EHR: it holds information and allows you to call it up on demand to support decision making. So it is decision support, but it's very light on algorithms and much more simply a way to vastly improve over paper and pencil as a way of recording and retaining and calling up information.

Then you have payers, who are looking at the studies that say that there's this huge percentage of clinical decisions, diagnostic decisions, therapeutic decisions, that are simply wrong, just unfortunately wrong. The rate of mistakes is very high, and so they're asking themselves, is there a way to use software to better support so that the doctor is reminded of the range of possibilities that a given situation might present.

Requiring provider-customized clinical decision support software to go through an FDA regulatory process would paralyze it, Thompson says.

A doctor might type in a bunch of symptoms and then the computer might say, 'Have you thought of these eight possibilities?' where maybe in their own minds they were only thinking of four of them, but the computer reminds them of other possibilities. The payers have a real strong interest in that. They are also looking at it beyond patient-specific stuff to more population-based stuff: Can we see trends, are there certain things that are underdiagnosed that we can alert physicians to be thinking about, as an example.

The providers use software for a variety of things. They focus on the patient as the customer and how to provide them with actionable information in order to get them to lead healthier lives. But also they look at these issues from an economy and efficiency standpoint. It's more a matter of automation of a lot of systems that touch the clinical environment, because that's the business they're in, but they also have almost an engineer's focus on the flow of decision-making and record-keeping and making a more orderly system out of the clinical environment.

And then you have medical device companies that maybe primarily come at it from, 'How do we use software to make our hardware devices more valuable so that the information flows from recognized medical devices into data sets that make the data more useful?' They almost approach it from a more accessory viewpoint.

Those are all different viewpoints, but they can be melded together. Our goal is to come up with a cohesive policy that describes what software should be in FDA regulation, and what software should fall outside of FDA regulation.

TGS: How much flexibility should hospitals and other providers be allowed in modifying clinical decision support software? Will this be part of the discussion?

Thompson: It will probably be part of the discussion, because it's hard to separate it. It's an important policy issue. Health care still, in many ways, is very decentralized. That's been the tradition in health care, and so there's usually a need for adaptation. Clinical guidelines vary from region to region; work flow, how doctors interact with patients and so forth, changes from region to region.

"The smart money is always on expanding FDA regulation. It's rare that the agency contracts its regulation."

Invariably there is a need to customize it. And requiring that customization to somehow go through an FDA process would just paralyze it. It would mean that everyone would have to follow a cookie cutter approach nationally.

And we've never favored a national health care system in this country; we've always supported local variation. In part it's because that's a way that innovation comes about as different regions experiment and find what works optimally.

I can't predict where we'll come out. Obviously, we haven't even gotten started. But I imagine that will be part of the discussion.

TGS: How will this impact regulation of electronic health records and electronic medical records?

Thompson: The complexity with EHRs and EMRs [electronic medical records] is that FDA keeps reaffirming – I think appropriately so – that they don't plan to regulate that kind of software.

The problem is that they've come out with at least two different software initiatives that seem to be intruding on the EHR space. One was the MDDS [medical device data systems rule] earlier this year, where basically they wanted to regulate those software programs that were used to take medical device data out of medical devices and put it in a repository. Well sometimes EHRs can be used for that. Sometimes EHRs could actually find themselves functioning as MDDS.

Then EHRs overlap in some measure with decision support software, because when you gather all that information up into an EHR, the temptation is, you've got all that data, let's start using algorithms to start analyzing that data that's in there. If you layer that algorithm program on top of it, there's a risk of transforming all of it into a piece of regulated software.

These days the lines between different types of programs seem to be blurring. That makes it more challenging to figure out what gets regulated and what doesn't.

That is, I imagine, the perspective that we'll have to analyze: FDA says EHRs are unregulated, but when does the intersection between EHRs and other programs in effect taint the EHR with regulation? Where do you draw the line in those situations? Those are very complex topics.

TGS: What advice would you give to medical device firms on how to begin preparing for possible policy changes involving clinical decision support software?

Thompson: It's so early that I don't really know where FDA is going to go with its regulation in this area. It makes it very difficult to give any specific advice.

The smart money is always on expanding FDA regulation. It's rare that the agency contracts its regulation. Those who may have found themselves in unregulated territory maybe because their software depended on manual data entry need to start seriously looking at when their products could end up being regulated.

But first and foremost, I would suggest that they get involved somewhere, whether it's at AdvaMed or it's with us or whoever it might be. Get involved in the process so that as it evolves, they can see more clearly and maybe with a little bit more advanced notice where it's going to go, and then prepare for it. Getting involved would maybe be my number one recommendation.