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What the Protecting Access to Medicare Act Means for Clinical Laboratories
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Guest: Dr. Paul Radensky is a Medicare law and policy authority who is board-certified in internal medicine and is an expert on federal legislative and regulatory processes related to Medicare coverage, reimbursement, and compliance.

Bob Barrett:

This is a podcast from *Clinical Chemistry*, sponsored by the Department of Laboratory Medicine at Boston Children's Hospital. I am Bob Barrett.

In 2014, the U.S. Congress passed the Protecting Access to Medicare Act (PAMA) which required CMS, the Centers for Medicare & Medicaid Services, to revise the clinical laboratory fee schedule to reflect private sector payment rates.

This change was in response to Government Accountability Office (GAO) and the Department of Health and Human Service Office of the Inspector General reports that indicated Medicare was paying significantly more for testing than private insurers paid. Legislators projected that the new law would reduce such spending by \$3 billion over five years. Many in the laboratory community believed that the cuts are too deep and have urged CMS to recalculate fees to more accurately reflect the spectrum of laboratories that provide testing for patients.

CMS however, has indicated that its current data collection model already accounts for most laboratory tests, and expanding the number of reporting facilities will not greatly alter the fees. Without change however, many laboratories are concerned that labs may scale back test menus or even go out of business. To gain greater insight on the potential impact of PAMA, a Q&A feature in the June 2019 issue of *Clinical Chemistry* asked six experts with different roles in this field to give their opinions on several of the key issues pertaining to the new reimbursement rates, particularly its potential impact on the laboratory marketplace and patient care.

We are pleased to have one of those experts in this podcast. Paul Radensky is a Medicare law and policy authority who is board certified in internal medicine and is an authority on federal legislative and regulatory processes related to Medicare coverage, reimbursement, and compliance. So, Dr. Radensky, let's start out by talking about the main issues regarding the laboratory fee schedule and why it seems to be so controversial.

Paul Radensky:

Sure. So, the clinical laboratory fee schedule was a creature of the early '80s where, at that point in time, they paid for most services based on charge profiles that docs had or that labs had or others had for various services, and it went by the terms UCR, Usual Customary Reasonable, Medicare called it Customary, Prevailing, and Reasonable, and basically, they would create charge profiles and somewhere in the middle is where they set rates and then over time, that got to be expensive so they would just keep putting caps on those charge profile-based rates.

Problems with that were twofold. One, for budgetary reasons, they just kept cutting and cutting, which meant that the only way you could keep up was by volume, because they were cutting, you know, the rates. There was an update factor that was in there but that was relatively minor and in most years, it was a zero so you really weren't able to, as new technologies would come in that might be more costly but they also provide advantages, there was no way really to capture that. Same time also as things got more efficient and cheaper, there was no way to capture that either. So, that was one major problem. You had a static fee schedule based on charge profiles in the early '80s.

And then you also had -- there were just -- things were dramatically unlike anything that ever was there in the '80s like molecular testing, and there was really no good way to analogize to the existing rates. So, given that, there were several ideas about how to reform the fee schedule and the PAMA approach was one to try and capture value, with the thinking that laboratories and private payers had incentives to set rates that reflected the value of the test much more than was there in the kind of charge-based profile Medicare fee schedule and so, having a private payer reference-priced system would allow for Medicare basically to recognize, do things that are of value when they come out and pay for them according to the value, but also to be able to capture back where things have gotten much less expensive and private payers were paying less.

That was the idea behind the new fee schedule. In order to do that, you needed to have a mechanism to collect data from laboratories about what are the private payer rates and so, CMS had proposed and then final rulemaking to try and address this and there was always a balance between -- well, if you think about all labs including physician office labs, you have something close to 150,000 laboratories and many, especially with physician office laboratories being over 100,000, they do a very limited portfolio of tests, both small portfolio as well as relatively small numbers.

And not wanting to burden them or some smaller labs, Medicare set thresholds for what the minimum number or volume by revenues labs had to have in order to report in. So, there was a dollar volume threshold of how much of the collections you have that are within lab fee schedule and Medicare dollars and there was another threshold for the proportion, how much of the revenues over your total Medicare revenues came from the clin lab fee schedule or the physician fee schedule. So, they're trying to focus on labs that did a fair amount of Medicare business and did a fair amount of Medicare lab business as their overall business.

Because of that structure that cut out a lot of labs, most physician office labs were excluded, most hospital labs were excluded, and even in the independent lab marketplace, it was excluding a fair number of labs. In addition, there were lots of labs that simply had no idea that this was out there and they needed to report, so you ended up having with the initial cycle of labs reporting a kind of universe of claims to set rates that was very much skewed toward the largest independent labs.

As you can imagine, those rates predictably could be lower than what you might find in smaller labs or in physician office labs where there's just different financial dynamics, because they're bidding with payers for a larger portion of the business. And so, there was a lot of concern that the new system, while theoretically should capture value, was in fact really capturing just the profiles of the largest reference labs. Now, for some of the laboratories that do just relatively high complexity -- I'm not talking from a CLIA complex perspective -- but just more advanced molecular types of testing and they have a very limited profile of tests that they do and they have been able to work with private payers and negotiate for rates that are commensurate with the value they think their tests offer. They've done fine under PAMA. That's kind of what the system was designed for.

But for many smaller independent labs or for physician office labs, having the rate structure dominated by the largest reference labs has been problematic. In addition, although there had been the thinking that given that the law passed in '14 and was going to be implemented in '17 and ultimately was implemented in '18, that payer contracts would reform and no longer peg to the Medicare fee schedule from what we understand has not happened, so that there are still a lot of payers who, in the fee schedules that they offer, laboratories offer a percentage off of Medicare which of course creates kind of a downward spiral because if Medicare is looking at the private payer rates to establish the Medicare rates and the private payers are

looking at the Medicare rates and paying only a discount off of that, you could have something that's going to continue to go down. So, the issues that we hear from especially the smaller independent labs, physician office labs, is that the rates are just not feasible for them, and also that they really have no ability to negotiate for the rates. So, those are kind of the key issues and how they arose.

Bob Barrett: What's your view on the effect that the PAMA cuts will have on development and adoption of newer technologies?

Paul Radensky: So, as you can imagine, if you have rates that are low or that are unstable, meaning that they're likely to go down over time, there's not particular incentive to create new tests that would fall under those rates. Again, where you have tests that might be completely unique, that there's nothing else that's like that out there, where we have had some of those, particularly in the molecular space headed by a sole laboratory, there -- I think, there are still incentives to innovate. Where you have things that might be innovations to make laboratories more effective but might have some incremental costs associated with them, that's going to be harder.

So, for example, most of the codes for clinical laboratory tests are analyte-specific but not method-specific, so if a better mousetrap is built that can improve the performance of the test and if there are costs associated with that, those aren't going to be captured because they'll be under an existing code and an existing rate. If you develop a test that's done at the point of care, oftentimes, in order to be able to get that through FDA with labeling at the point of care and then CLIA waiver, that requires a substantial cost to do that.

But if you're going to be under the same billing code and same payment rate, say as, the same analyte, but done in a large reference lab that's doing many times that volume and with an automated system not necessarily the in-office type of kit, it's not going to be feasible for those who develop those tests towards not having the incentive to develop those kinds of things that might be at the point of care. Many tests don't need to be at the point of care, but there are lots of tests where having the result with the patient in front of you is something that is beneficial.

So, I think those are particularly where we'll see issues with innovation. We do have a new code structure, so there is an opportunity for some other manufacture or lab who believes they've created a better mousetrap to get a code, they're called Proprietary Lab Analysis codes or PLA codes, and then you can try and get your own rate for that. But because the initial rate setting is by what's called crosswalk

or gap fill and usually crosswalk, they're likely to just crosswalk to whatever is the existing test for that same analyte. So again, not incentive to create the better mousetrap if you're just going to get paid the same as you would for that current mousetrap.

Bob Barrett: How will this new fee schedule affect point of care and near patient testing?

Paul Radensky: Yeah, continuing from what I was raising before. Oftentimes, when you have a test that is designed for point of care, particularly something that is CLIA waived, basically, you have to make the test so that it can be performed by non-laboratorians, kind of foolproof. And so, all the controls have to be built in. It has to be simple, it has to be something that really can be done with minimal manipulation at all of the specimen and in running it. That costs money to develop things like that. It also costs additional money to get a CLIA waiver over getting out from FDA. And all of that presumably -- those costs get capitalized and factored into the price of the test kit.

If that test for the point of care is going to be paid the same way as it would be in a large reference laboratory with a high throughput, then there's no way that a physician office lab will be able to afford because those kits tend to cost more. In addition, their portfolio of tests that they offer is relatively limited, the number of units of those tests by any physician office lab is typically also low, so, their overhead for the lab tends to be higher. So, there is a significant concern that access to point of care testing could reduce over time.

Bob Barrett: Do you believe these cuts will have a detrimental effect on patient access to care?

Paul Radensky: Yes, certainly I think, over time, that is the concern. We're only about a year and a half into the system so it's hard to tell for sure. Fortunately, there were guardrails built in to the system so the cuts in 2018 were limited to 10%, the cuts in 2019 a further 10%. But certainly, at some point, when you see for example that the medians in the 2017 data collection would set the rates for '18, most tests had very substantial cuts. There were lots of tests that had -- were projected to have 30% cuts over the three years, '18, '19 and '20. We'll have another data collection this year which presumably will lead to reporting in '20 and payment rates in 2021 where we have 15% corridors for those three years.

You add that up, you have basically a 75% potential reduction and at some point, it's just not going to be feasible for labs to continue, especially smaller labs, labs

with narrow portfolios, to continue to offer because there's nothing offsetting. If you have a broader portfolio, there may be some tests where you will have positive margins somewhere, you have negative and you can balance it, but if you have a narrow portfolio and they all have negative margins and go substantially further negative, it certainly can create access issues over time.

Bob Barrett: Well finally, I'm going to ask you to get your crystal ball out, polish it up and see what's coming up. If Congress makes no changes to the law, what do you foresee for the laboratory marketplace, say, in 2025, and do you think they will change the law?

Paul Radensky: So, let me kind of reverse order for that. Do I think that they will change the law? It's always difficult for Congress to act. It's never a trivial thing to get consensus and you need bipartisan support to get something through on the Senate in particular. And so, it's hard to say with any great likelihood that there will be changes.

And as I said, certain parts of the new system seemed to be working well, but I do think that there is more and more evidence of the concern about some of the broader impacts, particularly on broad range of laboratories and especially as you get to some of the more common tasks that there, as I said, continues to be pegging to the Medicare rate, which is just a downward spiral. There definitely are efforts by a number of lab stakeholders to try and put some type of brake on this and to come up with a reporting process that is more representative. I don't think stakeholders are necessarily saying "throw this whole thing out" because I don't think that's realistic, but trying to get rates that would more closely reflect the overall marketplace. So, for example, if you have a test that is predominantly done in the physician office lab setting, but the rates that you're using to establish that really are from the reference lab setting, not the physician office lab setting, you're really not reflecting the marketplace.

And so, I do think that there is a reasonable shot that Congress will try and take some steps to try and make this more representative. That said, anything that they do, you have to balance if that's something that's going to cost the system money to hold it up for a bit or to slow it down for a bit. And so, that's the part of the difficulty I think in crystal balling whether or not Congress will act, but there definitely does seem to be some recognition in Congress that the system isn't necessarily operating overall as intended in that there may be some areas where corrections are needed.

If they don't make any corrections, what do I see? I think there will be substantial consolidation in the lab

marketplace. From what I hear at least, and I don't always have first-hand evidence of what the financials really look like, but certainly, from the things that we've heard and certainly it makes sense given where the rates are, that a lot of laboratories are having a very difficult time with the reduced rates. Given that I think we would likely see a lot of consolidation among the independent lab marketplace, I think we may well see a reduction in offerings by physician office labs, and it may have an impact on what kind of tests are developed, particularly for those marketplaces.

Bob Barrett:

That was Dr. Paul Radensky, who is a partner in the law firm of McDermott Will & Emery based in Washington, DC, and a Medicare law and policy authority. He is one of the experts that participated in the Q&A feature in the June 2019 issue of *Clinical Chemistry* on the laboratory fee schedule implemented under the Protecting Access to Medicare Act. I'm Bob Barrett. Thanks for listening.