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AdvaMedDx Steps Into Public Sphere: Director Details Diagnostics Priorities

The recently established diagnostics arm of AdvaMed had what its executive director called a coming out party last week.

AdvaMedDx - formed as an "association within an association" in late 2009 - sponsored its first conference June 22 in Washington D.C., targeting the core mission of the group: to get the word out about in vitro diagnostics and what the tools bring to the health care system.

But public affairs is not the group's only focus. It has also taken on AdvaMed's core lobbying goals in the in vitro diagnostics space, including efforts to realign FDA oversight to be completely risk-based, regardless of whether tests are kits or lab services, and to reform the Medicare payment system for advanced diagnostics. (See “AdvaMedDx’s New Chairman Is BD Exec Vince Forlenza” - “The Gray Sheet” Oct. 25, 2010.)

AdvaMedDx Executive Director Andrew Fish sat down with “The Gray Sheet” at the June 22 symposium, which served to introduce the various areas of focus in the diagnostics industry.

“The Gray Sheet”: What was the purpose of this meeting and what do you hope to gain from it?

Andrew Fish: The overall purpose of this meeting for AdvaMedDx was to educate a wide-range of stakeholders about the impact and value of in vitro diagnostics. We know as an industry that we contribute in a very great way to the entire continuum of care, from screening and diagnosis all the way through treatment, and we want to make sure that message is getting out to stakeholders. We look forward to partnering with a wide-range of stakeholder organizations to help deliver diagnostic innovations to patients.

TGS: How many members do you currently have in AdvaMedDx? Do you have members that are makers of laboratory-developed tests?

Fish: We currently have 65 members. We represent only companies that are manufacturers of FDA-cleared or approved diagnostic tests. Lab-developed tests are made of course by labs, which are not members of ours unless they have one or more FDA-cleared products. Our membership is manufacturers, as opposed to labs.

TGS: What have been the most important actions AdvaMedDx has taken in its short life thus far?

“What AdvaMedDx is bringing to this industry is more focused, across-the-board advocacy, in particular, on public affairs” - Andrew Fish

Fish: One thing that's important to note is that representing the diagnostic industry is not new to AdvaMed. AdvaMed has had a very robust representation in this industry for many years, so we have some very well established areas of activity, particularly in the regulatory and reimbursement areas, that continue. What AdvaMedDx is bringing to this industry is more focused, across-the-board advocacy, in particular, on public affairs - much like this event today was designed to get out the word on diagnostics, and to reach out to and partner with a wider range of organizations. Of course, what we hope to do over the longer term is to find common cause with a range of stakeholder organizations to advance our policy goals in the regulatory and reimbursement areas.

TGS: FDA is in the middle of updating some its diagnostics policies, and in particular the agency is creating a regulatory framework for laboratory-developed tests. What do you want to see included in that effort?

Fish: We have been consistently calling for FDA to take a risk-based approach to regulation of all diagnostics, regardless of where they are produced or used. Of course, we are expecting FDA to make some announcements in this area before long. We're encouraged by what FDA has said that it will adopt a new approach and implement a number of risk-based criteria for regulating diagnostics, so that's obviously an area of significant interest for us.

TGS: Do you have an idea when FDA will issue the draft guidance?

Fish: We had expected that it would be as early as this summer, but FDA is juggling a lot of other priority areas, including 510(k) reforms and putting together the new user fee reauthorization package. (See "FDA: Draft Guidance For Laboratory-Developed Tests Regs Taking Extra Time" - *"The Gray Sheet" April 25, 2011.*)

TGS: In parallel to the FDA effort, Sen. Orrin Hatch, R-Utah, has circulated draft legislation to reform diagnostics oversight. How is AdvaMedDx engaged in the process?

Fish: We are very pleased that Senator Hatch and other members of Congress are taking an interest in diagnostics. We welcome that level of attention as an opportunity to talk about our industry and its value. (See "Senate Bill Would Create New Diagnostic Center At FDA" - *"The Gray Sheet" April 4, 2011.*) We have been working with Senator Hatch's office, as have a number of other stakeholders. We appreciate his view that regulation of diagnostics needs to be modernized, certainly in keeping with the principles that we've advanced at FDA. I think Senator Hatch is continuing to work on that draft bill, so I don't know where that will go, but we'll certainly keep working with his office on these issues.

TGS: What priorities does AdvaMedDx have with the ongoing user fee reauthorization talks?

Fish: I can't speak specifically to issues that are under negotiation with FDA. I can only say broadly that in the IVD area, as in general for medical devices, we would like to see more timely access for patients to our products and that means getting through the FDA approval process in an efficient manner. And we'd certainly like to see that work better for our member companies.

TGS: What are your top line priorities for improving reimbursement for diagnostics, particularly molecular tests?

Fish: The issue of reimbursement is certainly a great challenge in the diagnostic area. Diagnostic reimbursement is primarily based on the Medicare Clinical Lab Fee schedule which was established in 1980's and hasn't been significantly updated since then. So even as we develop substantial and really ground-breaking innovations at significant costs and significant regulatory approval times,

those contributions are not recognized in any significant measure by the current reimbursement system. This is a huge priority for us. It's our overall view that for significant innovation to continue in this field, payment systems need to be modernized to reflect the contribution of diagnostics. That's probably a longer-term initiative. I do expect Congress to take an interest in this issue and there will be those who support our overall view, but it's a challenging budget environment.

TGS: Is there any particular piece of legislation that could be a vehicle for such a provision?

Fish: We've been working with the National Health Council on some draft initiatives that I expect could be seen in legislation soon. We're very pleased to be working closely with them and a wide range of their constituents on an initiative that could be helpful in the reimbursement area. (*See box.*)

TGS: Are you working with CMS to make incremental improvements on diagnostic reimbursement?

Fish: We have been certainly keeping up communications with CMS. The key area right now, not just from a reimbursement perspective but really an overall coding and coverage standpoint, is working on the new proposed codes for molecular diagnostics. The AMA [American Medical Association] Molecular Pathology Workgroup has proposed a series of new codes for molecular diagnostics that would provide significant transparency into the precise test being performed. It remains to be seen how those specific tests will be reimbursed by CMS, what rates they would set for those tests. That's an ongoing issue we're working closely with CMS on.

TGS: Besides the National Health Council, what other groups is AdvaMedDx collaborating with on the reimbursement issues?

Fish: Several organizations are examining this reimbursement challenge and studying a variety of different policy solutions and we are in communication with all of those organizations at one level or another. There has certainly not been a consensus policy proposal that has surfaced. But it is a high priority issue that all of us are really focused on.

BIO has been studying this issue. They commissioned a report by a consultant a few months ago that did not reflect a specific adoption of a policy, but surveyed a number of possible policy alternatives in this area. (*See "BIO Plans Lobbying Push To Improve Payments For Diagnostics " - "The Gray Sheet" Jan. 10, 2011.*)

Draft Dx Legislation

The National Health Council, an umbrella organization for patient advocacy groups, clinical societies and industry associations, is circulating draft legislation on Capitol Hill called the "Modernizing Our Drug & Diagnostics Evaluation and Regulatory Network Cures Act." It has a likely sponsor in the House, but NHC is still seeking a champion in the Senate, the group says. In diagnostics, the bill would:

- Require FDA to issue guidance on the co-development of diagnostics and drugs within a year of enactment.
- Improve Medicare's coding and reimbursement system for innovative diagnostic tests, including the establishment of an independent advisory board to advise CMS on payment for new tests.
- Create incentives to encourage the development of diagnostics that help predict the appropriate patient population and treatment option.
- Create a council to develop educational tools to improve the understanding of key diagnostics concepts.

○ *Source: The National Health Council*

PhRMA is obviously looking at this issue as well.

And then a number of other organizations, including ours, are discussing this issue within the Personalized Medicine Coalition. (See "Personalized Medicine Coalition Renews Pitch For Modern Coding System" - *"The Gray Sheet"* Dec. 13, 2010.) There's a common recognition of the challenge, and partly given the budget environment and partly because of the complexity of this matter the policy proposals are a little less obvious.

TGS: What other policies you are focusing on in Congress or with FDA?

Fish: In the current budget discussion we're very much on guard for possible proposals to add Medicare co-pays or co-insurance for diagnostic tests, which would of course, in our view, be something that could inhibit patients from getting the tests that they need. (See "Labs, Test Makers To Finance Committee: Say 'No' To Medicare Co-Pay" - *"The Gray Sheet"* Aug. 10, 2009.)

By Rebecca Kern

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