LDT proposal on the radar—little detail, clarity needed

Latest on laboratory staffing and solutions

December 2023—*For most, laboratory staffing woes continue, despite some letup post-pandemic.* CAP TODAY *publisher Bob McGonnagle on Nov. 7 got a sampling of where staffing stands as the year end approaches, in his conversation online with members of the Compass Group, an organization of not-for-profit IDN system lab leaders who collaborate to identify and share best practices and strategies. But first a few words from them about the Food and Drug Administration's proposed rule on laboratory-developed tests.*

The FDA issued its proposed rule for laboratory-developed tests, and comments are due in early December. Greg Sossaman, what are your thoughts on it at this time as it relates to Ochsner?
Gregory Sossaman, MD, system chairman and service line leader, pathology and laboratory medicine, Ochsner Health, New Orleans: It's very much on the radar here. We were looking at a new sequencing laboratory where we would do germline testing for BRCA and Lynch syndrome, and we've put it on the back burner because we don't know what is going to happen with LDTs.

We as individuals don't have enough details to prepare; the document doesn't stipulate anything specific we can do. There doesn't appear to be a route yet by which something could be submitted. Until the details are provided, it's watch and wait for us at Ochsner, although I'm working now, as an individual, with other groups to see how they plan to respond.

Mike Eller, what is your perspective from Northwell?
Mike Eller, assistant vice president of business development, Northwell Health Laboratories, New York: I agree with Greg—it's wait and see. They've given us very little to prepare, very little to go off of, so it's a waiting game.

Bull

Tony Bull, your thoughts on the proposal?
Tony Bull, system administrative officer, Pathology and Laboratory Medicine Integrated Center of Clinical Excellence, Medical University of South Carolina: I regard the proposal as chilling for innovation and development of new testing. We saw with COVID what can happen when there are bottlenecks in developing tests. I encourage all of us to be vocal about it, to get involved in it. It's bad regulation, and I don't see a good way for this to work. I don't know how the FDA will handle the volume of approvals. I'm not sure it has the funding; I think somehow we'll end up paying for it. And ultimately it won't serve our patients well.

Peter Dysert, MD, chief, Department of Pathology, Baylor Scott & White Health, Dallas: It wouldn't hurt to get together the leaders of the various professional organizations to write a consensus statement. If nothing else, instead of an open meeting, they could write a letter, with signatures, on behalf of those organizations, one that could be published online and elsewhere to get attention. We need to have a sharp message and eliminate the noise so it can be heard.

I am going to turn to the topic of staffing and ask Autumn Farmer how Bon Secours is faring.
Autumn Farmer, MHA, chief laboratory officer, Bon Secours Mercy Health, Cincinnati: We're doing much better than the past two years. We're anticipating a little resurgence in our vacancy rate in '24. Our human resources has a team tracking this and looking at potential retirement dates; they feel we're going to have a gap. We're also

worried because our health system has cut some funding for tuition repayment, and in talking with students we're finding they will go elsewhere if you don't have that.

Stan Schofield, do you foresee things getting worse with staffing? And can you comment about how systems can provide help to their member laboratories on staffing issues, including schools, tuition reimbursement, and career enhancement?
Stan Schofield, VP and managing principal of the Compass Group (formerly of NorDx/MaineHealth): It will be more challenging for them to provide help going forward because roughly 60 percent of all hospitals are still in the red and are having to cut anything that's not producing revenue. These fringe cuts and reductions are common at most hospitals and health systems in the United States. They have no new revenue streams and cannot get ahead of nursing contract labor costs or traveling support staff costs. Hospitals are also seeing more and more denials and hand-to-hand combat with insurance companies.

Staffing at NorDx and MaineHealth is better than it was a year ago but not great; instead of 18 percent vacancies, it's 14 percent. The number one suggestion by staff is, "We need more staffing." The second is, "We want more money."

I don't see hospitals coming up with extra money for laboratory automation solutions. Many of them are saying, "If you can't do it with what you have, then we will monetize you as an asset."

In other words, they're cutting reasonable long-term investments to meet short-term needs. Is that fair to say?
Stan Schofield (formerly of MaineHealth): Yes. Just to keep the lights on.

Angela Boast, what is the labor situation in Arkansas?
Angela Boast, quality assurance laboratory manager, University of Arkansas for Medical Sciences: Pretty good. We are struggling with finding histotechnologists, but for the most part the lab is well staffed.

Joe Baker, can you give us a rundown on what you've been doing about staffing in Dallas?


Baker

Joseph Baker, VP of diagnostic services, Baylor Scott & White Health, Dallas: We have been nimbler in our process for interviewing and making offers. We are competing with many competitors in all our markets across Texas, and now we can interview and make an offer faster to get new team members into our lab system. We've aligned our sign-on bonuses criteria so we're not self-competing with each other in key areas.

We expanded our in-house accredited MLS program, which is making a difference and supports our long-term vision. Prior to expansion, we graduated about eight to 10 students a year and would retain about 50 to 60 percent. Our program has now expanded to our north Texas region. We're doing two classes a year instead of one, and we anticipate having 36 graduates over the next year with a goal of retaining around 75 percent of those students.

We are currently investigating a histology and a cytology training program to be part of our existing education program. We must grow our own to be successful because the candidates aren't out there. Overall we've successfully decreased our number of openings by about 40 percent post-pandemic.

Would it be fair to say that, like Stan, you still have a shortage that is tangible to your work effort?
Joe Baker (Baylor Scott & White): Yes. We have shortages in key geographic regions. We are seeing significant

increases recently of our laboratory leaders retiring, deservedly, and we don't have the resources to mentor our next leaders to succeed them.

I'm hearing increasingly that there's a rapid retirement cliff of senior laboratory leadership and administrators, and it's proving to be difficult to replace them. Do you agree?
Joe Baker (Baylor Scott & White): I agree. Our challenge is we have the talent internally but don't have the time to fully get them to a place where they feel they can succeed and be confident.

Rebecca Phillips, can you comment on staffing at Ochsner?

Dr. Phillips

Rebecca Phillips, MD, system chair for anatomic pathology, Department of Pathology and Laboratory Medicine, Ochsner Health, New Orleans: We have a chronic staffing issue. The main way we will succeed long term is to grow our own, whether it's partnering with a local community college in the medical technologist arena, providing on-the-job training for histotechnologists, or working with pathologist assistant schools to make sure we're a rotation site for cytotechnologists, et cetera. When we try to increase market, our higher leadership is worried about the market comparison inching up one site versus another locally and creating a false inflation.

Winnie Carino, what is your staffing situation at Scripps?
Winnie Carino, MA, CLS, MLS(ASCP), director of laboratory services, Scripps Health, San Diego: We have the lowest number of openings in years. Almost all our CLS or MLS positions were filled this year. We do have the challenge of our younger CLSs not being quite ready yet to become leads or supervisors.

Our CLS training program has helped the most. Each year we have about 130 applicants but spots for only six students a year. This means we're able to select the best of the best and retain them as well.

It's challenging in San Diego because there are a lot of biotech companies, so we worry about the competition with that industry. We try to show our students the advantages of staying with our organization and offer sign-on bonuses, which helped, especially for the night-shift positions.

Does anyone have a comment or question for the group?
Dr. Dysert (Baylor Scott & White): In Texas we have rather extreme weather situations that put a stress on our existing staffing shortage. It seems the public schools in our areas close more frequently now for bad weather. A large hospital like ours is used to having 18 phlebotomists each morning to collect the run. If bad weather prevents them from coming in, we might have one or two. Has anyone proactively gone to their workforce and solicited people whose family situations allow them to work an extended period of time? What are others doing, beyond tabletop or theoretical exercises, to plan for weather-related or mass casualty events?

Michele Erickson-Johnson, you're from a part of the country where the roads get about as bad as they can get, and you have a huge geography. What kind of planning do you have for protracted bad-weather situations in the Dakotas?

Dr. Erickson-Johnson

Michele Erickson-Johnson, PhD, HCLD/TS (ABB), MB(ASCP)CM, senior director of laboratory operations medical genetics and biorepository and enterprise laboratory quality, Sanford Laboratories, and assistant professor of internal medicine, University of South Dakota Sanford School of Medicine: Last winter our parking lot inadvertently wasn't plowed, so we had staff stranded in the building. We provided emergency supplies and cots and sleeping bags for them to spend the night until they could get dug out. We've since fixed that problem. In Bismark, staff will spend the night at a hotel across the street if they can't get home or make it back to work. People will volunteer to pick up staff in their four-wheel-drive vehicle and bring them to work. One person was picked up by snowmobile to get to work. We get creative when the weather gets bad.

Tony Bull, what concerns do you have in Charleston?

Tony Bull (MUSC): We are in a fault zone, so earthquakes are a concern. Hurricanes are another. We have a lot of bridges, so one consideration is how we can get our staff to the hospital if the bridges are out. We're doing an emergency exercise next week related to that.

Stan Schofield, how has MaineHealth prepared for bad weather?

Stan Schofield (formerly of MaineHealth): We've managed to stay open during snowstorms and shutdowns. All external phlebotomy, patient service centers, nursing homes—everything gets dropped or reduced with as much notification as possible, and we bring everybody into the home hospital and get it done. Maine Medical Center has almost 700 beds, so we have to bring everybody in. Even if we had to send people out in four-wheel-drive vehicles to pick up staff and bring them in to draw blood, we would. Lack of staffing in these situations has happened enough that this became our approach—pull everyone inside the fort walls and stay there and protect it.