An area of CLIA that needs serious scrutiny is that of the waived testing and the subsequent consequence of waived labs. When the laws were first written, there were only a handful of waived (mostly-home), simple tests, and the waiver might have made sense in that environment. There was also consideration of physician office labs and access to testing for their patients. Now however, there are hundreds of these tests and diverse "laboratory" settings. Manufacturers have also seen this as an opportunity to de-centralize the laboratory market and increase distribution. These are not necessarily negative outcomes- as the simplified tests have increased patient access to robust tests and have been a springboard for improved technology and innovation. As a consequence, though, the waived test space is occupied by many molecular tests that provide results that inform some very medically complex situations. While the technical aspects of the tests may meet the CLIA waived criteria, it seems that the whole process – the implementation and continued operation in the current diverse practice settings is not considered with the current regulations. This could not be foreseen in 1988. The results of many waived tests as implemented, cannot be considered to have "insignificant risk". Allowing organizations to provide medical testing services for fees and to provide results for patient management puts the US behind many other countries that require at least a rudimentary level of quality for all "non-self" medical testing services- and especially those being submitted for fee or reimbursement.

As you know, labs with a certificate of waiver do NOT have to comply with the quality management regulations in CLIA. So, while they may follow manufacturers' IFU's, the other necessary and basic requirements such as training, personnel competency, proficiency testing and overall quality control are voluntary for >70% of CMS registered/ certified labs in the US. I have tried to bring this up at professional association meetings after hearing presentations of the atrocities of waived testing in good institutions that are under the umbrella of a quality management system. Unfortunately, LDT oversight issues have usurped lab leaders' attention and resources. In addition, the professionals in these associations are not the problem. They are striving to correct infractions in their organizations.

Somehow, the law or the regulations need to be changed to require that any entity performing a test (even waived) on individuals for medical reporting (and for reimbursement or pay), must comply with at least minimum standards of quality such as test verification, personnel training, continued competency, proficiency participation, test requisition and reporting minimum requirements, and ongoing quality monitoring. (For example: what happens to all those technical bulletins the manufacturer sends - some of which may require a lookback? Do the lab reports sent out have the required information? Who/ how is ongoing quality monitored? Who advises clinicians on interpretation and limitations?) In addition, CMS should be resourced to actively inspect these labs or outsource the inspections.

CAP/ COLA/ AAB/TJC certified, and CMS CLIA compliant labs all conduct their waived testing under their quality management systems. Why should 70% of the labs in the US be able to test without having to adhere to at least a rudimentary standard of continued quality? These same organizations, along with our government organizations (CDC, CMS, etc.) have provided extensive resources for those waived labs that want them, however, if they are not mandated to follow certain rules, many may not seek or incorporate these.

We may not even know the full scope of the problem. CMS was going to inspect at least 6% of CMS certified CLIA waived labs. They inspected about 2% early in the 2000's and found many

infractions. The program stopped, and I am not sure there have been resources to restart this effort. Since waived laboratories are not mandated to subscribe to any ongoing quality or PT, we do not even have PT data on the continued performance of these tests in these settings. We only have data from those labs that voluntarily subscribe or those that perform waived testing with waived products in certified labs. (Even then, while the PT organizations have this data, CMS does not collect or review it.)

One of the documents for this meeting records some discussions about the CLIA Waiver laws- years ago. I also see that it is an item for the CLIAC discussion. I hope that this issue will not be continually dismissed as we grapple with the increasing complexity of LDT oversight and other legitimately pressing issues. One of the speakers today stated that many of the issues discussed at today's meeting existed before the pandemic but have been heightened during this episode. As stewards of medical laboratory testing, it is our duty to get a handle on this growing segment of our profession. Non-laboratory professionals and the general public do not understand the regulation nuances to distinguish CLIA-waived from CLIA certified/ compliant labs when they read or hear about improper testing – and our profession should steward all forms of testing under the CLIA process.

Yes- CLIA needs an overhaul. (And CMS needs more resources!) And in that, we must address the issue of the CLIA "waiver" and waived labs. Unfortunately, the CLIA-waived concept is in the statute. Perhaps there is a way to modify regulation by adding a risk category such that an entity providing test services for "non-self" would have to adhere to a considerably basic modified area of the regs such as those I stated above.

Thank you for your consideration of these points, and for your continued work and efforts in assuring the quality and availability of timely and relevant clinical laboratory tests and processes.

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