Jesse Caplan

General counsel

Massachusetts Executive Office of Health & Human Services

February 19, 2016

Dear Mr. Caplan,

I respectfully submit the following comments specific to the revision of 105 CMR 180.000: *The Operation, Approval and Licensing of Clinical Laboratories*. I commend the Department’s efforts in streamlining and simplification of the state licensure process and wish to add the following comments in hopes to enhance the goals of this revision.

180:004: Definitions: Genetic Tests

“Gene-expression detection” should be added as labs are also performing RNA tests that should be regulated under the same construct.

Also, With the CMS definition of an ADLT, this definition should also include “or a combination of analysis with an algorithm to produce a result”

180.030: (B): (1): (d,f):

There may be difficulty in demonstrating items in (d) without patient samples. Is the intent to demonstrate with patient samples, but not report results from genetic testing until after the initial survey? If it is should the restriction in (f) be “the laboratory shall not report results from patient testing until…”?

180.030: (C):

Add “Molecular Immunohematology” as a sub-specialty of Immunohematology

180.030: (A):(6)

If a lab was under investigation for fraud (such as reimbursement fraud) with the outcome of the investigation still pending, the current language still allows for licensure. Is that the intent?

180.033:(J):

The language specifies “written” test results. Some results may be provided in e-format (text, email, or app that accesses a database). I would think this should be more flexible.

180.035:

Since LDTs are under the jurisdiction of the FDA, I would recommend adding or other agencies with appropriate jurisdiction.

180.042:(B):(3)

For labs in MA, this will limit any acquisition of specialty labs that have a unique LDT that would be difficult to transfer to a different location (parent facility) due to specialized equipment, and personnel requirements. With Next Gen Sequencing (NGS) becoming attractive platform for a variety of new test offer, forcing its placement in a parent may slow down adoption of new innovations in MA.

180:044:(A)

There are some specialized, non-stat tests that are cost effective when batched. TAT would vary in these cases and may not be as clearly defined. In these cases, the definition may be a range of TAT or a justification of not having a defined TAT.

180.500: (B): (1)

This section may not accommodate certain practices. For example, in hospital blood banks, there is typically not an order for genetic/molecular testing, only an order for compatible units. The blood bank director typically makes the decision to perform genetic testing, as they are the ones responsible for blood component compatibility.

180:500: (C): (2)

If the laboratory uses an FDA approved or cleared test, can the laboratory use the manufacturer’s IVD status with documented IFU as test performance documents?

180:500: (C): (5):

It would be beneficial to have this section in to more updated definitions by CMS and FDA:

IVD (FDA approved or cleared)

LDT (Laboratory developed test…designed, manufactured, processed in the lab)

RUO (Research use Only)

IUO (Investigational use only)

180:500: (E): (1): (k)

FDA and CMS have classified tests as IUO, RUO, LDT and IVD and has required manufacturers to label kits appropriately. CMS considers only LDT and IVD tests reimbursable and submitting for reimbursement for any other test type as fraud (lots of labs under investigation for this). I think reports need to include the regulatory status of the test(s) used as documented by the manufacturer. This protects the laboratory and gives guidance to payment coders.

Thank you for the opportunity to submit these comments. Please do not hesitate to contact me with any questions.

Sincerely,

Joel de Jesus

Sr. Director, Government Affairs & Payer Relations

Immucor, Inc.

35 Technology Drive

Warren, NJ 07059