Checklist, CLIA line up on COVID reporting

Anne Paxton

November 2020—It's been well understood since the Ten Commandments that rules that appear simple in theory can be fiendishly complex or even impossible to execute. The pandemic is providing a perfect example of that in the laboratory world, but with added twists, at least for now: It may not be clear which rules are mandatory, desirable, or optional—and those aren't the only sources of confusion.

Since March, much attention at the federal level has been focused on clear standards for reporting results of SARS-CoV-2 testing. But many fear that new rules to standardize reporting could require hammering a multitude of diverse square pegs into round holes.

The main points of contention and sources of confusion over the rules, as set forth June 4 in Health and Human Services reporting guidance and the CLIA regulations for COVID-19 result reporting (QSO-20-37-CLIA), have been the type, number, and format of data elements that would be required. "The initial set of requirements, the amount of data that was requested to be collected, and the uncertainty of what CMS would enforce put labs in a precarious situation," says Raj Dash, MD, a member until last month of the CAP Board of Governors. "As the HHS guidance was originally written, it was untenable for many labs, particularly smaller labs, to comply with."

At present, labs will be penalized only if they fail to report both positive and negative test results to their state and local public health authorities. While the June 4 guidance is required, the Centers for Medicare and Medicaid Services has said it will enforce only a few key aspects.

An eAlert announcing a checklist revision to GEN.41316 (Infectious Disease Reporting) designed to align CAP laboratory accreditation requirements with the changes in the CLIA regulations has been sent to all CAP-accredited labs, and that requirement will be the basis for any type of CAP review or audit inspection, Dr. Dash says. The new checklist requirement says that labs subject to U.S. regulations that perform testing intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 must report positive and negative results to local or state health authorities "in a standardized format and at a frequency specified by the Secretary of HHS to include all molecular, antigen, and antibody test methods used with all types of CLIA certificates." The checklist revision to GEN.41316 is effective immediately for all laboratories.

The actions still required of laboratories are to work with their local or state public health authorities to ensure that all required COVID-19 testing results are reported and to have records available (electronic or paper) to show the reporting is occurring.

Reporting both positive and negative results breaks with established practice for infectious disease reporting, which usually requires reporting of only positive results. Since the current requirements are only part of an interim rule, the concern is that more could be forthcoming. HHS initially proposed additional standards and those may still be under consideration.

The data elements that could be required later are answers to what has been labeled ask-on-order-entry questions, such as whether the patient is symptomatic as defined by the CDC or if the patient is pregnant.

Both the interim final rule and HHS reporting guidance are sufficiently worrisome that even though HHS contends they are necessary to help it manage the pandemic, the CAP has requested publicly and in private meetings that they be rescinded.

Dr. Carter

The CAP's concern grew when HHS issued COVID-19 reporting requirements geared to the pandemic. "The June 4 guidance included 18 'required' data elements plus a huge number of others that were 'requested,'" says Alexis B. Carter, MD, physician informaticist, pathology and laboratory medicine, Children's Healthcare of Atlanta. "You would have been required to make every reasonable effort to report that data, and there was a deadline of August 1—but no specifics about what would be the penalties for lack of compliance."

Moreover, she notes, "There was a lot of conflicting and contradictory information in the reporting requirements that indicated they were put together in a hurry. The federal government was asking for data we had never been asked to provide in public health reporting previously. So laboratories were confused about what they need to do."

Then the CMS issued an interim final rule (CMS-3401-IFC) that outlined penalties for both hospitals and laboratories that did not comply with the HHS reporting requirements.

"This is a big change for CMS to do this," Dr. Carter says, "and it would be a big change for CLIA-deemed agencies that accredit laboratories," including the CAP, to revise their requirements to comply. The interim final rule became effective Sept. 2. But at the CAP's request, the CMS agreed to a three-week grace period with a compliance date of Sept. 23. The CMS has told CAP leaders it is not currently enforcing the 18 data elements. However, many reporting requirements, both actual and potential, remain to be clarified.

Dr. Olson

Confusion reigns now over which regulatory requirements are in effect and which are tabled indefinitely because different federal agencies responsible for health regulation have advocated different proposals. "There are a lot of layers and there is a lot of information coming at folks," says Jordan Olson, MD, division chief, clinical pathology informatics and quality, Geisinger Medical Center, Danville, Pa. "Everybody's saying, 'Oh, we need to do reporting,' but then everybody has their own flavor of what exactly they want. And that's been hard to deal with."

The initial 18 required data elements, though they pose challenges, are comparatively clear; it's the requested data elements that look difficult to impossible to many in the laboratory world. As Mick Scanlan, MD, chairman of the CAP Council on Accreditation and vice chair of clinical pathology at Oregon Health and Science University, says, one silo of the government—that is, HHS, or essentially the executive branch—"is asking for all this additional information that we can't get very easily."

While some of the requirements have been put on hold for now, more clarity would be helpful because there have been conflicting signals from different federal agencies and the White House/HHS, Dr. Carter says. "The interim final rule says we have to follow the original reporting requirements or we are subject to civil monetary penalties. But when we've had lectures or webinars from CMS on this topic, they've indicated that, at least initially, they will only look at whether we're reporting positives and negatives."

The data elements to go with the result reports are the problem. As Dr. Carter points out, many of the data

elements mandated in the HHS reporting guidance have never been required before—for example, inclusion of the test system's FDA unique device identifier (UDI). "I don't know of a single lab that has done that. On top of that, the vast majority of the tests have an emergency use authorization from the FDA and don't have a UDI." In addition, rules such as those that require HL7 reporting format would mean changes to laboratory information system interfaces for which LIS vendors charge fees.

Also not fully appreciated is that the test results are to be reported to the public health laboratories of the individual's residence. "We have seen patients from 27 different states outside Georgia," Dr. Carter says. "It might be easy if all states accepted faxes but they don't. California and Alabama, for example, require electronic entry into a portal and it takes days to get access and training for that, while Texas requires a secure file transfer protocol that takes weeks to get set up." There could also be a serious problem of states duplicating reports, she adds, which could cloud data being used to gauge the spread of SARS-CoV-2 infection.

The concept of "ask on order," in general, may not be as useful as intended, she believes. "Hospitals are already reporting a good bit of this data such as whether a patient is hospitalized. It isn't clear how asking these questions at a test order level will be helpful."

The confusion that issues like these create has led to many laboratories being unable to report, she says. "I've heard that only 26 percent of laboratories were doing any reporting," amid the supply shortages and other difficulties they face.

Potential penalties for laboratories failing to report correctly are also unclear, Dr. Carter says. "CMS initially said it would strictly fine laboratories based only on whether they are reporting positives and negatives, and it did not necessarily plan to look at each data element. But when we had meetings with the local CMS branch, the message was much different. The letter of the law says we have to comply."

The CAP began expressing concern to the CMS about reporting requirements in April or May, says Helena Duncan, CAP assistant director, public health and scientific affairs, who has been in direct contact with the federal oversight agencies about the reporting requirements.

After the CARES Act passed in March, the plan to require clinical laboratories to report positive and negative results was communicated, and the CAP believed the HHS guidance went far beyond what was in the CARES Act and would exceed laboratories' resources, Duncan says. "Initially we wanted to talk with them about either simplifying the reporting requirements or easing the burden on laboratories by creating templates that could be integrated into the laboratory information systems so reporting would be an automated process."

But the June 4 guidance seemed to up the requirements even further. "It was a lot more detailed and requested information beyond the lab's control and scope, such as ask-on-order-entry questions."

Given that SARS-CoV-2 was a new strain of the SARS virus, Duncan says, "we were supportive at first of reporting positives or negatives to better understand the prevalence of the disease. The reporting up to that time was inconsistent and we needed all the states to be reporting the same information. The June guidance just went well beyond what we felt was necessary."

Dr. Scanlan

Typically, Dr. Scanlan says, when a state public health agency tracks influenza or tuberculosis cases, only positive cultures are reported. "That's the structure that's been in place forever," he says. "And the focus of the state

public health laboratories is on contact tracing," which is why they are interested only in positives. "Here, the government wants more data about the infection's spread and what's going on, so that's why they are requiring all this excessive data."

One reason both positive and negative test results began to appear necessary to the CMS was the difficulty of identifying COVID-19 hotspots, he explains. "Some locations had 100 percent positivity, which was not believable."

The data elements to be required may not be capped at 18. Requirements mentioned by the CDC have 24 elements, including the test platform on which the test was performed, Dr. Scanlan says.

He worries about the impact of the penalties labs could face for noncompliance with the rules. "On the first day of noncompliance, you're fined $1,000, and then $500 per day." Accreditation issues have also arisen related to the reporting requirements, he says, one of which is how to deal with labs if they don't comply. "We do need to report noncompliant labs to CMS if they are not reporting. And we can discover that through a live inspection, through a complaint, or by other means." To encourage compliance, the CAP accreditation program has developed a paper insert for the inspection packet to help laboratory inspectors focus on the issues around COVID, which include such areas as safety.

From Dr. Dash's perspective at Duke University Health System, the HHS guidance has been challenging because there are two sets of requirements, one for the hospital and one for the laboratory.

'We continue to ask CMS and CDC to rescind the June 4 guidance document until they can implement a workable solution.'
—Helena Duncan

"The laboratory is focused on COVID-19 testing"—the DNA, antibody, and antigen tests. "On the hospital side, it contains aggregated diagnostic testing data but also reflects other elements of the hospital, such as pharmaceuticals and availability of ICU beds, that would be outside the purview of the laboratory. So it requires close coordination to ensure that we're leveraging the same data sources, not skipping a segment of the population or a certain set of orders, and that the numbers jibe across the health system where you have multiple hospitals, multiple clinics, and testing occurring at patients' bedside or in some samples traveling to a central lab and being tested there. Those results all need to be aggregated daily and sent to the government agencies, which include our county, our state, and the CDC as well."

The speed with which data had to be provided was also difficult. "If there are data elements the White House feels it's important to collect, they want to start collecting them right away, not wait months for implementation as you would normally for bringing a change into an information system." The normal procedure, Dr. Dash notes, would involve a regimented process for identifying requirements, building the system, validating the platform, bringing it

into production, and having another round of evaluation and metrics after it's gone live. "That's not the same cadence with which labs have been asked to respond in the COVID-19 setting."

But it's also been unclear which elements are most important, what is required and enforced, and what is optional. "We can make assumptions about what the data is going to be used for, and sometimes we scratch our heads on why they're asking about one data element but ignoring others."

Epic has created a user community to let customers crowdsource answers to questions and resolve ambiguities. For example, for an answer to the question about pregnancy, "they would go out to the EMR and if they were able to find a recent pregnancy test, they would answer yes to questions that they knew were yes, as a default, although the provider would be able to change the answer. So at least the provider wouldn't have to check the chart and fill in the value."

'It's just not possible for every health care organization to report to every state agency.'
—Raj Dash, MD

The mandate from the agency is for laboratories to fill out the answer as best they can. But since "unknown" is one of the answer options, Dr. Dash says, "it's very easy for a provider or reference lab to just put 'unknown' for all the responses simply because it would be a great deal of work, or onerous, to collect the data and validate that the answers are accurate." Some reference labs have created a new specification to get the answers at the time the order was placed, but others may be hard-coding the word "unknown" into those responses, he says. Duke has devoted a lot of time and effort to meeting the reporting requirements. "We are fully compliant. But not everyone has access to our resources. So the regulations ask that you do the best you can, and I think that's where we are today."

Supply chain limitations and thus the need for labs to use multiple platforms means a lot of IT infrastructure, he says. "We've had to create a mechanism whereby the microbiology lab and their staff can take a sample, decide that day they have more reagent in a particular instrument and run the test on that instrument, then the next day run it on a different platform that needs to work with the same order. That requires IT expertise and effort to move specimens around across different platforms and have the LIS recognize where results from different instruments need to be paired together for the right patient."

The patchwork of methods and instruments can be difficult to coordinate into one smooth reporting system, even theoretically, Dr. Dash says. "You have the county, the state, CDC, FEMA sometimes, ultimately CMS now, and HHS receiving data and it's unclear what the level of data integrity is," especially when there is a high risk for duplication of results where results are being reported interstate. It's unclear how those issues are being resolved, he says.

"It's just not possible for every health care organization to report to every state agency," Dr. Dash says. The state agencies should be the ones doing the coordinating among themselves so that there is one clean data set for

every lab that exists in a particular state, in his view.

“If I were a data scientist,” he says, “I would have very little confidence in the data that’s being aggregated nationally, because of the disparities inherent in the ambiguous reporting requirements.”

These reporting issues are unprecedented, Dr. Dash notes. “There’s never been a pandemic of the scale of COVID-19 and in 20 years I’ve never been in a position of having to go to such extraordinary efforts to provide the level of testing needed on a daily basis for our patients. And with this level of complexity, the public health reporting complexities are magnified.”

The CAP has been working with the federal agencies to clarify the reporting requirements, Dr. Carter says, and continues to believe that the requirements should be rescinded based on the level of confusion and difficulty. For now, Dr. Carter says, “Laboratory directors need to know what the requirements are in their state and whether or not their state department of public health is reporting to outside states, because if not, it’s the laboratories’ responsibility to do it. And they should be aware there are civil monetary penalties attached to noncompliance.”

The CAP has also been working on its comments in response to the interim final rule (due Nov. 2), which support reporting only the positive and negative data elements to public health labs, Duncan says. The CAP believes that “we should focus on the public health labs, ensure that they can accept the information, and then have the clinical labs report the data to the public health labs.”

“We continue to ask CMS and CDC to rescind the June 4 guidance document until they can implement a workable solution that is not sort of piecemeal. I think they’re very wedded to the document, and they are encouraging people still to try to comply with the guidance.”

But, she adds, “we haven’t seen or heard that HHS is going to take action; they don’t have a mechanism to enforce the 18 data elements. We know CMS can do an inspection or survey based on a complaint and assess if a laboratory is reporting, but they’re not making a special trip to do this. So our interpretation—what we’re advising labs—is that this is what CMS is requiring and what you must comply with. But labs will only be subject to enforcement action if they don’t report positive and negative results.”

Although the CDC has said that a lot of labs are compliant, Duncan says, “we don’t know if they are referring to one data element or 18.”

“We’ve been trying to educate our members to make sure they understand, and we report on this regularly in our advocacy newsletter and update our FAQs so they are aware of changes.” Labs are encouraged to report as many data elements as they can but to focus on reporting positive and negative results. “Some states have told people they won’t be able to accept this data until December. But you still have to have documentation that you attempted to submit results to the public health department, even if they won’t accept it,” Duncan says.

Her advice to labs: “Do your best in reporting and documenting your efforts to report, and if you have any issues, contact the CAP advocacy office because we’re interested in hearing about any problems or issues you are having.”

If the penalties had not been included in the agencies’ rules, says Dr. Olson of Geisinger, fewer people would be reporting as many data elements. In addition, “If the guidance were clearer about which items are truly required versus requested versus optional, we probably wouldn’t be doing as much reporting. But because there’s so much confusion, at Geisinger we’ve gone with a conservative approach to say we’ll try to report everything they’ve asked for, which has been very hard to accommodate.”

At Geisinger, this has meant spending several hundred hours of IT analyst time trying to get this reporting set up and tested. But Dr. Olson doesn’t see a way around the effort and the expense. “I would love it if HHS or CMS would change the requirements. I’m not sure if that’s a realistic expectation, though, at this point.”

Anne Paxton is a writer and attorney in Seattle.