

Chapter 1

Ministry of Health

Section 1.07

Laboratory Services in the Health Sector

Follow-up on VFM Section 3.07, *2017 Annual Report*

RECOMMENDATION STATUS OVERVIEW

	# of Actions Recommended	Status of Actions Recommended				
		Fully Implemented	In the Process of Being Implemented	Little or No Progress	Will Not Be Implemented	No Longer Applicable
Recommendation 1	2	2				
Recommendation 2	1			1		
Recommendation 3	1	1				
Recommendation 4	3	2	1			
Recommendation 5	4		2	2		
Recommendation 6	3		3			
Recommendation 7	2		1			1
Recommendation 8	3	1	2			
Recommendation 9	2		2			
Recommendation 10	2		2			
Recommendation 11	1	1				
Recommendation 12	1			1		
Total	25	7	13	4	0	1
%	100	28	52	16	0	4

Overall Conclusion

As of October 31, 2019, the Ministry of Health (Ministry) had fully implemented 28% of actions we recommended in our *2017 Annual Report*, such as establishing a process to regularly assess and update the price list for community laboratory services; implementing a process to regularly identify

potential unnecessary laboratory tests; and identifying underserved areas for community specimen collection centres.

The Ministry has made progress in implementing an additional 52% of the recommendations, such as working with Local Health Integration Networks to encourage hospitals to adopt consistent laboratory test ordering guidelines; establishing regional targets to monitor and

assess the availability and accessibility of community specimen collection centres; conducting an analysis of the costs and benefits of moving toward a regional laboratory system; and establishing standard performance targets and measures for community and hospital laboratories.

However, the Ministry has made little progress on 16% of the recommendations, which include analyzing the capabilities and responsibilities of different types of laboratory service providers (community, hospital and Public Health Ontario) to determine if any changes are needed with respect to the types of tests each provider performs and evaluating the existing provincial capacity and funding for genetic testing to determine whether they are sufficient to meet the growing demand.

One of the recommendations, related to assessing the costs and benefits of short-term versus long-term performance-based contracts with community laboratory service providers, is no longer applicable.

The status of actions taken on each of our recommendations is described in this report.

Background

Laboratory services involve the collection, testing and analysis of a patient's specimen (such as blood, urine or stool) for health-care professionals to make decisions on the diagnosis and treatment of their patients. Various studies note that laboratory tests inform and guide over 70% of medical decisions.

Ontario has about 400 specimen collection centres where specimens are collected from patients, and about 200 laboratories where the collected specimens are analyzed. In 2017/18, the Ministry of Health and Long-Term Care (Ministry) spent about \$1.9 billion (\$2.0 billion in 2015/16) funding about 270 million tests (260 million in 2015/16) performed by:

- community laboratories (operated by private companies);

- hospital laboratories;
- health-care professionals (mainly physicians) who perform tests in their own offices; and
- Public Health Ontario laboratories.

Health-care professionals are responsible for ordering laboratory tests for their patients. Once the specimens are collected from patients, they are sent to a laboratory for analysis. In addition to community and hospital laboratories, Public Health Ontario laboratories also perform testing for infectious diseases, such as HIV and hepatitis.

Our audit in 2017 found that laboratory services were generally provided to Ontarians safely, and accurate laboratory tests results were generally provided to health-care professionals in a timely manner. However, there were several areas relating to cost-effectiveness, accessibility, and performance measurement and reporting of laboratory services that needed improvement.

The following were some of our significant observations:

- The Ministry had not made any major updates to its price list (which is the price it pays to community laboratories for each test they perform) since 1999. It planned to implement a new price list in 2017/18. If this new price list had been in effect in 2015/16, the Ministry would have paid community laboratories \$39 million less that year.
- The Ministry had not regularly evaluated whether currently uninsured tests, such as CA 125, used to measure the amount of protein cancer antigen in a patient's blood, should be funded, even though many of these tests have become more widely accepted as medically necessary and are often funded by other provinces.
- The Ministry's actions to reduce unnecessary testing, such as Vitamin D testing, did not result in effective or sustainable long-term reductions in testing.
- The Ministry's strategy for genetic testing resulted in costly out-of-country testing. Between 2011/12 and 2015/16, the Ministry

paid over US\$120 million related to over 54,000 specimens sent out of the country. While the cost to perform some genetic tests would be cheaper if these tests were done in the province instead of out of country, the Ministry's strategy to increase in-province genetic testing was still preliminary.

- The Ministry had not regularly reviewed billings by physicians who performed laboratory tests on their patients. We identified 120 family and general practice physicians with large test volumes and billings. The 15 with the highest billings each performed between about 75,000 and 182,000 tests, and billed between about \$600,000 and \$1.4 million in 2015/16 (about 128 to 300 times the average billings of a typical family and general practice physician). The Ministry had performed only a limited number of reviews to verify the accuracy of these billings.
- Physicians did not require a licence to perform in-office laboratory testing and were not required to participate in the province's quality management program. This was raised as a concern in our 1995 and 2005 audits, as well as in external studies, but the Ministry had taken no action over the past two decades.

We made 12 recommendations, consisting of 25 action items, to address our audit findings.

We received commitment from the Ministry that it would take action to address our recommendations.

Status of Actions Taken on Recommendations

We conducted assurance work between April 1, 2019 and August 1, 2019. We obtained written representation from the Ministry of Health (Ministry) that effective October 31, 2019, it provided us with a complete update of the status of the

recommendations we made in the original audit two years ago.

Overpayments to Community Laboratories

Recommendation 1

To ensure that payments made to community laboratory service providers are reasonable, we recommend that the Ministry of Health and Long-Term Care (Ministry):

- *establish a process to regularly assess and update the price list for community laboratory services based on actual community laboratory cost data and input from industry experts;*

Status: Fully implemented.

Details

In our 2017 audit, we found that while technological advancements led to significant automation and cost reduction for many laboratory tests, the Ministry had not made any major updates to its price list (which defines the type and price of each test that the Ministry pays community laboratories to perform) since 1999.

In our follow-up, we found that in July 2019, the Ministry finalized a manual, called *Policy, Process, and Procedures for Managing the Schedule of Benefits for Laboratory Services*. The purpose of this manual is to guide the Ministry's decision-making and to ensure that the Ministry regularly assesses and updates the price list for insured community laboratory services. The Ministry has established processes for updating the price list.

In October 2018, the Ministry also established a Test Review and Utilization Committee (TRUC), which is composed of industry experts. The Ministry will continue to engage with the TRUC to gather cost data sources that will help them assess the laboratory sector's price list. At the time of our follow-up, five meetings with the TRUC had been held since October 2018, and the Ministry had scheduled two more meetings to be held in fall 2019.

- *regularly collect and assess cost information from community laboratory service providers to ensure the amount paid by the Ministry is based on relevant information.*

Status: Fully implemented.

Details

In our 2017 audit, we found that the Ministry planned to update its price list for 2017/18, but the draft new price list was not based on actual cost data from all community laboratory service providers in Ontario. This was because the Ministry did not have access to any financial information from community laboratory service providers under the fee-for-service arrangement with the providers.

In our follow-up, the Ministry indicated that this recommendation will not be implemented because the community laboratory service providers, which are private corporations, are not obligated to provide cost information to the Ministry. During their negotiations to establish a Transfer Payment Agreement with the Ministry, community laboratory service providers did not agree to share their cost information.

We noted, however, that the Ministry had taken action to address our recommendation. Instead of collecting cost information from the community laboratories directly, the Ministry was planning to obtain the information from other sources, such as through the Test Review and Utilization Committee (TRUC) and from its own research.

Fragmented Management of Laboratory Sector

Recommendation 2

To ensure that laboratory services are appropriately funded and performed effectively and efficiently to meet patient needs, we recommend that the Ministry of Health and Long-Term Care analyze the capabilities and responsibilities of different types of laboratory service providers (community, hospital and Public Health Ontario) to determine if any changes are needed with respect to the types of tests each provider

performs and, accordingly, the amount of funding each provider receives.

Status: Little or no progress.

Details

We found in our 2017 audit that some interrelationships existed between different types of laboratory service providers—for example, hospital laboratories may refer complex tests for infectious diseases to Public Health Ontario laboratories. Nevertheless, the Ministry had not done any analysis to determine whether laboratory services were provided to Ontarians efficiently and effectively, in a cohesive manner, to meet patient needs and to save overall health system costs.

In our follow-up, we found that the Ministry had not analyzed the capabilities and responsibilities of different types of laboratory service providers to determine whether any changes were needed regarding the types of tests each provider performs and the amount of funding each provider receives. While the Ministry had not completed a full review of the hospital and public health laboratory sector, it had begun work on one by first focusing on modernizing the community laboratory sector and other insured laboratory programs (such as colorectal cancer screening).

As mentioned in action item two of **Recommendation 1**, the Ministry considered a business case to engage a consultant with expertise in laboratory sector systems, processes and pricing. At the time of our follow-up, the Ministry was reviewing alternate approaches to address this recommendation.

No Regular Review of Medically Necessary Tests

Recommendation 3

To ensure that Ontarians are able to access and pay fair prices for the medically necessary laboratory tests they require, we recommend that the Ministry of Health and Long-Term Care analyze the current list of uninsured tests in Ontario (particularly those identified by the consulting firm it engaged) to determine

the medical appropriateness of these tests and how these tests are funded in other jurisdictions, and to formally decide whether to fund any of these tests and at what prices.

Status: Fully implemented.

Details

In our 2017 audit, we found that in 2015/16, health-care professionals in Ontario ordered about 1.1 million laboratory tests that were not funded by the Ministry. Patients generally had to pay community laboratory service providers for these uninsured tests out-of-pocket or through their private insurance. The Ministry had not regularly evaluated whether these uninsured tests should be funded, even though many of these tests have become more widely accepted as medically necessary and have been funded by other provinces.

In our follow-up, we found that the Ministry has established a process for analyzing the current list of uninsured tests in Ontario to decide whether to fund any of them. As mentioned in **Recommendation 1**, in October 2018, the Ministry established a Test Review and Utilization Committee (TRUC), which is composed of industry experts. The TRUC provides advice to the Ministry's Laboratories and Genetics Branch on the clinical utility, validity and value of new and existing laboratory tests. The TRUC will continue to review potential new tests for addition to the Schedule of Benefits for Laboratory Services (Schedule). The Ministry will request feedback from stakeholders and the TRUC on adding new tests to the Schedule in order to determine whether any new tests should be funded by the Ontario Health Insurance Plan (OHIP).

More Action Needed to Reduce Unnecessary Testing

Recommendation 4

To ensure that the use of unnecessary tests is effectively managed, we recommend that the Ministry of Health and Long-Term Care:

- *implement a process to regularly identify potential unnecessary laboratory testing by monitoring test volume increases, requesting unusual test ordering patterns from laboratory service providers, and reviewing academic research studies available in the field;*

Status: Fully implemented.

Details

In our 2017 audit, we found that the Ministry's actions to reduce unnecessary testing, especially relating to vitamin D testing and aspartate aminotransferase (AST) testing (usually used to identify liver damage), did not result in effective or sustainable long-term reductions in testing. Ontario studies found that both of these tests were being ordered in situations where the result was not useful in improving the health of a patient.

In our follow-up, we noted that the Ministry and community laboratories had agreed on establishing a number of working committees in spring 2019 to discuss matters related to laboratory services, which include implementing a process to regularly identify unnecessary laboratory testing. The following actions, as mentioned in **Recommendation 1**, will also address this recommendation:

- In October 2018, the Ministry established a Test Review and Utilization Committee (TRUC), which is composed of industry experts. The TRUC provides advice and input to the Ministry's Laboratories and Genetics Branch on the clinical utility, validity and value of new and existing laboratory tests. The TRUC also provides advice on the appropriate use of laboratory testing. At the time of our follow-up, five meetings had been held since October 2018, and two more meetings had been scheduled to be held in fall 2019. Ongoing meetings with the TRUC will help the Ministry identify potential unnecessary laboratory testing.
- In July 2019, the Ministry finalized a manual called *Policy, Process, and Procedures for Managing the Schedule of Benefits for Laboratory*

Services. One of the policy statements of the manual is to ensure that “insured laboratory services are provided only when medically appropriate. Test volumes are monitored for unnecessary testing.” The Ministry has implemented a new process relating to this policy. Following this process, the Ministry retrieved data on AST testing and analyzed it with the TRUC. As a result, the Ministry sent notices to 118 corporations with 143 laboratory hospital sites regarding inappropriate AST testing and asked them to submit plans for correcting their practices.

- *establish a process to regularly revise and improve the existing test ordering guidelines and restrictions to eliminate or reduce unnecessary tests;*
Status: Fully implemented.

Details

In our 2017 audit, we found that the Ministry set guidelines on when a laboratory test could be ordered by a health-care professional in an effort to reduce unnecessary testing. However, it was up to health-care professionals and community laboratory service providers to follow those guidelines.

In our follow-up, we found that the Ministry was establishing a process to regularly revise and improve test ordering guidelines and restrictions to eliminate or reduce unnecessary tests. As mentioned in **Recommendation 1**, the Ministry finalized a manual called *Policy, Process, and Procedures for Managing the Schedule of Benefits for Laboratory Services*. The manual specifies processes for developing test ordering guidelines and restrictions to eliminate or reduce unnecessary tests. The manual also includes a process to enforce adherence to these guidelines and restrictions. The Ministry is now using the clinical expertise of the Test Review and Utilization Committee (TRUC), mentioned in **Recommendation 1**, to help develop and update these guidelines and restrictions.

- *work with Local Health Integration Networks to encourage hospitals to adopt consistent laboratory test ordering guidelines.*

Status: In the process of being implemented by December 2020.

Details

In our 2017 audit, we found that the Ministry and Local Health Integration Networks (LHINs) did not require hospitals to have laboratory test ordering guidelines or initiatives. Such guidelines would help to ensure that hospital funding was used to perform only necessary laboratory tests.

In our follow-up, we found that, since November 2018, the Ministry’s Laboratories and Genetics Branch has engaged other branches within the Ministry to encourage the LHINs and hospitals to adopt consistent laboratory test ordering guidelines. The outcome of initial discussions among different branches was favourable and the Ministry had prepared to distribute test ordering guidelines to the LHINs and hospitals. The Ministry had also received early interest from several LHINs (including Champlain, Waterloo Wellington, Toronto Central and Hamilton-Niagara-Haldimand-Brant) to analyze data and physician ordering patterns within their regions. The Ministry will continue to work with the LHINs on the implementation of this recommendation while the transition to Ontario Health continues.

In addition, the Ministry has been working with the Institute for Quality Management in Health-care (Institute) on updating the accreditation requirements checklist under the Institute’s quality management program. Part of the accreditation requirements checklist will include managing laboratory test ordering and use. The accreditation requirements checklist is scheduled to be published in December 2020.

Inadequate Strategy for Genetic Testing Results in Costly Out-of-Country Testing

Recommendation 5

To ensure that genetic testing is provided to Ontarians appropriately and cost-effectively in a timely manner, we recommend that the Ministry of Health and Long-Term Care:

- evaluate the existing provincial capacity and funding for genetic testing to determine if they are sufficient to meet the growing demand for genetic testing and genetic counsellors;

Status: Little or no progress.

Details

In our 2017 audit, we found that the Ministry had not kept up with the growing demand for genetic testing. Ontario's medical system had lagged in investment, infrastructure and development of expertise in this area. As a result, many genetic tests had been sent out-of-country, at a significant expense to the Ministry.

In our follow-up, we found that the Ministry had not evaluated the existing provincial capacity and funding for genetic testing. The Ministry indicated that such an evaluation requires a comprehensive review of the current system first, including gathering data on test costs; however, this review had not yet started at the time of our follow-up. The Ministry was considering engaging a consultant with expertise in laboratory operations and test costing, and was planning to then begin an evaluation of the current state and provincial capacity for genetic testing using available data. The Ministry was also considering reviewing alternate approaches to address this recommendation.

While the Ministry has not evaluated the existing provincial capacity and funding for genetic testing, the Ministry indicated that it had taken some action to address the growing demand for genetic testing, by for example:

- continuing to implement the recommendations by the former Genetic Testing Advisory

Committee and other expert working groups (such as the Rare Disease Working Group and the Epilepsy Genetic Testing Criteria Working Group) to develop criteria that aid clinicians in determining the appropriateness and benefits of genetic testing for patients;

- participating as an ex officio member of the Ontario Genetics Advisory Committee at Health Quality Ontario to help ensure that best available evidence and relevant economic analyses are used in funding decisions for new genetic tests; and
- evaluating the out-of-country claims data to determine which genetic tests have the highest volumes and costs and which may be most appropriate for establishing in Ontario.
- analyze the costs and benefits of current genetic testing providers to determine the most appropriate provider of each genetic test for Ontarians;

Status: Little or no progress.

Details

In our 2017 audit, we found that while community laboratory service providers were capable of performing genetic testing, the Ministry prohibited them from performing these tests, except for three specific cases: non-invasive prenatal testing, tuberous sclerosis testing and retinoblastoma testing (to detect a form of eye cancer).

In our follow-up, we found that the Ministry had not analyzed the costs and benefits of current genetic testing providers to determine the most appropriate provider of each genetic test for Ontarians. The Ministry indicated that before doing such an analysis, an operational review of the current genetic test providers is required. However, such a review has not yet started. The Ministry informed us that it will begin to develop a list of genetic test providers and analyze the current genetic tests available in Ontario.

- *continue to process out-of-country genetic testing applications within turnaround time targets to prevent recurrence of a backlog;*

Status: In the process of being implemented by December 2020.

Details

At the time of our audit in June 2017, we found that the Ministry took, on average, 48 business days to process most out-of-country applications for genetic testing, significantly longer than its 14 business-day target. Following our audit fieldwork in July 2017, the Ministry eliminated this backlog by hiring additional staff and streamlining its process.

In our follow-up, we found that the Ministry had met the turnaround time target for processing out-of-country genetic testing applications. The Ministry indicated that it implemented several initiatives to avoid future backlogs. Examples of the initiatives include:

- In spring 2018, the Ministry's Laboratories and Genetics Branch requested the Ministry's Business Innovation Office (Office) to assess the future operations of the program that provides prior approval for out-of-country and out-of-province laboratory and genetics testing. In July 2018, the Office issued recommendations, such as simultaneous electronic editing and tracking of applications; clarifying and sharing eligibility criteria with physicians; introducing an electronic application process; and producing weekly or monthly reports for managers to stay abreast of the trends of applications. The Ministry plans to implement the Office's recommendations by December 2020.
- In spring 2018, the Ministry's Laboratories and Genetics Branch sought approval for hiring additional administration support for out-of-country and out-of-province claims due to the high volume of applications. While the additional staffing was not approved, the Ministry said it is adjusting internal staffing to provide support until the additional position is approved.

The Ministry will also continue to look at opportunities to patriate genetic testing in Ontario in order to reduce out-of-country applications.

- *work with Local Health Integration Networks and hospitals to develop provincial wait-time targets for genetic counsellor services, regularly measure actual wait times against these targets, and take corrective action if the targets are not met.*

Status: In the process of being implemented by December 2020.

Details

In our 2017 audit, we found that the Ministry had not measured and monitored whether patients had access to counselling services for genetic testing on a timely basis. As a result of the growing demand for genetic testing, patients had experienced long wait times to see genetic counsellors.

In our follow-up, we found that since November 2018, the Ministry's Laboratories and Genetics Branch had been having conversations with its Ministry counterparts on genetic counsellors, and had met with other branches within the Ministry relating to the LHINs and hospitals to raise awareness of the importance of setting and measuring wait time targets for genetic counsellor services. The Ministry will continue to work with the LHINs on the implementation of this recommendation while the transition to Ontario Health continues.

The Laboratories and Genetics Branch plans to have further discussions with other Ministry divisions by December 2020.

More Effort Needed to Improve Underserved Areas of Community Laboratory Services

Recommendation 6

To ensure that Ontarians have timely access to community laboratory services, we recommend that the Ministry of Health and Long-Term Care:

- *establish regional targets to monitor and assess the availability and accessibility of community specimen collection centres;*

Status: In the process of being implemented by December 2020.

Details

In our 2017 audit, we found that the Ministry had not established a provincial target for the availability of collection centres across the province. It had only set a target for rural areas: 90% of rural Ontarians are to be within a 30-minute drive of a collection centre. Although the Ministry met this target for rural areas, it did not consider the differences in capacity (such as operating hours or the number of blood-drawing chairs) that could affect how many patients the collection centres could serve.

In our follow-up, we found that the Ministry had not established regional targets to monitor and assess the availability and accessibility of community specimen collection centres. However, the Transfer Payment Agreement between the Ministry and community laboratories includes a requirement that community laboratories submit a report called Access and Specimen Collection. The report provides the Ministry with data on specimen collection centres' access points and their availability during the week (such as hours of operation).

The Ministry's Laboratories and Genetics Branch was planning to develop a methodology to first measure the accessibility of community specimen collection centres with the help of other Ministry counterparts with expertise in geographical information systems and to discuss the development of methodology. The Laboratories and Genetics Branch indicated that it would continue to work with its Ministry counterparts to establish data collection processes and data storage, and develop regional targets related to such data.

The Laboratories and Genetics Branch also indicated that it will review the opening and closing hours of specimen collection centres (which are access points for laboratory services) and the results from its Health Care Experience Survey

(given by telephone to Ontarians aged 16 years and older) as sources of information to consider for the development of regional targets for access to laboratory services.

- *collect and analyze the operating hours, locations and distribution of community specimen collection centres on a regular basis (such as annually);*

Status: In the process of being implemented by June 2020.

Details

In our 2017 audit, we found that the Ministry did not collect useful information on collection centre capacity (such as operating hours or the number of blood-drawing chairs) throughout the province. Without this information, it was not clear whether the Ministry's actions had resulted in the appropriate availability of community laboratory services across the province, especially in underserved areas.

As mentioned in the action item above, the Ministry requires community laboratories, as part of their Transfer Payment Agreement, to submit a report called Access and Specimen Collection, which provides the Ministry with data on specimen collection centres' access points and their availability during the week (such as hours of operation). The Ministry has been working on developing a template for the report by June 2020. The Transfer Payment Agreement also includes specific provisions that address patient access in hard-to-serve regions and high-needs areas. The Ministry's Laboratories and Genetics Branch indicated that it will continue to work with other branches within the Ministry to establish data collection processes and data storage, and develop regional targets related to such data.

- *identify underserved areas for community specimen collection centres and take corrective action.*

Status: In the process of being implemented by June 2020.

Details

In our 2017 audit, we found that Ontario had relatively fewer specimen collection centres than other provinces. The collection centre rate (including both hospital and community collection centres) per 100,000 people in Ontario had been low in comparison with other jurisdictions.

In our follow-up, we found that as part of developing its Northern Rural Laboratory Services Strategy (Strategy), the Ministry engaged a consultant to assess laboratory services in northern rural Ontario. The goals of this assessment include reviewing the current state of laboratory services in northern rural Ontario—including laboratory infrastructure, technologies, partnership relations, and funding for community laboratory services—as well as identifying the strengths and improvement opportunities for community laboratory services in that region. Recognizing that a one-size-fits-all solution is not workable in northern rural Ontario, the Ministry and the consultant took the following actions between October 2017 and March 2018:

- conducted two surveys with all 36 hospitals in the North East LHIN and North West LHIN to assess the current state of laboratory services and to determine the volume of community laboratory tests done by hospitals;
- met with the Small, Rural and Northern Provincial Leadership Council of the Ontario Hospital Association; and
- held several in-person consultations with the LHINs and hospitals.

In April 2019, the consultant submitted the final report to the Ministry. The report concluded that “in communities that are not served by a community laboratory provider, hospitals provide a designated ‘outpatient’ collection service ... 96% of the population in northern rural Ontario is within a 30-minute drive of its specimen collection centres.” Therefore, instead of focusing on access to specimen collection centres, the Ministry indicated that a practical definition of access in northern rural Ontario must also include access to testing facilities, efficient and cost-efficient transportation

of specimens, timely results, and effective communication of results to the primary care physician, hospital and patient.

The Ministry informed us that it will continue to explore these issues in developing the Strategy through additional consultations with stakeholders. The Ministry also had further discussions with the consultant during the first quarter of 2019, seeking clarifications on some of the content provided in the report.

Inadequate Oversight of Community Laboratory Services

Recommendation 7

To ensure that community laboratory service providers operate effectively and efficiently and bill accurately for tests actually performed, we recommend that the Ministry of Health and Long-Term Care:

- assess the costs and benefits of short-term versus long-term (recommended by the Laboratory Services Expert Panel in 2015) performance-based contracts with community laboratory service providers;

Status: No longer applicable. A different assessment will be conducted.

Details

In our 2017 audit, we found that the Ministry had not consistently tied its payments to community laboratory service providers to their performance because the Ministry had not established and tracked useful performance measures to monitor the community laboratory sector.

In our follow-up, we found that this recommendation was no longer applicable because the Ministry had already executed a Transfer Payment Agreement for insured laboratory services with each of the seven community laboratory service providers. The term of each agreement is six years, with the ability to negotiate toward the end of the term for amendments or a new agreement.

The Ministry is currently in the third year of the six-year agreement. The Ministry said it is not considering changes currently to the term or other provisions in the agreement, but will revisit options at a date closer to the end of the agreement (in March 2023).

- *reinstate periodic reviews of community laboratory service providers to verify that the laboratory tests they billed were actually performed.*

Status: In the process of being implemented by December 2020.

Details

In our 2017 audit, we found that the Ministry used to conduct audits of community laboratories to verify that the tests they performed and billed were supported by signed physicians' requisitions. However, it stopped conducting these audits in 2013.

In our follow-up, we found that the Ministry's Transfer Payment Agreement with each community laboratory service provider includes an audit and inspection provision related to funding and activities performed. The Ministry is currently in the third year of a six-year agreement. The Ministry said it will begin a process for spot checking and audits in 2020.

The Ministry's Laboratories and Genetics Branch had also begun investigating issues relating to billings and worked with the Health Services Branch on how to communicate with community laboratories about these issues.

The Laboratories and Genetics Branch, which is also part of the Ministry's internal Fraud Control Working Group, plans to develop a process for audit and periodic reviews of community laboratory service providers to verify billings, and develop a process for fraud control by the end of 2020.

Inadequate Oversight of Physicians' In-Office Laboratory Testing

Recommendation 8

To ensure that billings by physicians for their in-office testing are accurate and physicians are performing these tests properly, we recommend that the Ministry of Health and Long-Term Care:

- *identify and collect information on physicians' practices with high volumes of in-office testing and high billing amounts related to these tests, on an ongoing and timely basis;*

Status: In the process of being implemented by March 2020.

Details

In our 2017 audit, we found that physicians could perform point-of-care tests that are generally simple to do (such as urine dipstick tests that detect pregnancy and abuse of drugs). However, the Ministry did not check the accuracy of all physicians' billings related to performing these tests, including those who billed much higher than the average physician for in-office laboratory testing.

In our follow-up, we found that the Ministry's Laboratories and Genetics Branch had analyzed testing volumes and billing for certain tests to identify potential savings. The Ministry's Health Services Branch had also initiated provincial reviews to investigate billing patterns and outliers of an individual or group of physicians that warrant a detailed review. This is an ongoing process and may include physicians who have a pattern of high billings for certain services. The Ministry was drafting proposals for changes to the post-payment review and education processes of physicians to address this recommendation by March 2020.

- *investigate physicians whose billings related to in-office testing are not supported by the information collected;*

Status: Fully implemented.

Details

In our 2017 audit, we found that between 2011/12 and 2015/16, the Ministry only reviewed the billings related to eight of the 120 family and general practice physicians who billed much higher than the average physician for in-office laboratory testing. The Ministry collected some information during these reviews to understand the size of the physicians' practices. However, in the majority of cases, the Ministry did not collect details on the size of top-billing physicians' practices to determine whether they accurately billed for laboratory testing provided to their patients or whether they possibly billed the Ministry inappropriately for laboratory testing not performed.

In our follow-up, we found that since January 2018, the Ministry investigated 91 physicians whose billing had an in-office laboratory testing component. For each of these investigations, the Ministry did not identify any inappropriate billing related to laboratory testing. In addition, the Ministry had not received any notice of possible inappropriate billing specifically related to in-office laboratory testing since January 2018, and therefore had not opened any post-payment reviews for this type of billing.

- *implement quality assurance requirements for laboratory tests done in physicians' offices.*
Status: In the process of being implemented by December 2020.

Details

In our 2017 audit, we found that physicians were still not required to be licensed by the Ministry to perform laboratory services as reported in our 1995 and 2005 audits on laboratory services. They continued to be exempt from participating in the quality management program, even though in 2015/16, physicians performed 10.6 million in-office tests.

In our follow-up, we found that the Ministry was considering an approach for implementing quality assurance requirements for laboratory tests done in physicians' offices. In November 2018, the Ministry

contacted the College of Physicians and Surgeons (College) to discuss a quality management program for laboratory tests done in physicians' offices. The College recommended that the Ministry send a formal letter to the College on this request. The College will then review whether it could be addressed as part of its priorities in 2019. The Ministry also plans to meet with the College on this request in order to address this recommendation by December 2020.

Inadequate Oversight of Laboratory Services Provided by Hospital Laboratories

Recommendation 9

To ensure that best practices are shared between hospital laboratories to improve the co-ordination and consistency of hospital laboratory services, we recommend that the Ministry of Health and Long-Term Care work with Local Health Integration Networks and laboratory service providers to:

- *conduct an analysis of the costs and benefits of moving toward a regional laboratory system;*
Status: In the process of being implemented by December 2020.

Details

In our 2017 audit, we found that while some hospitals worked together to develop regional laboratory networks that resulted in cost savings, this practice was not widely adopted across Ontario.

In our follow-up, we found that the Ministry had been working with the LHINs to consider conducting an analysis of the costs and benefits of moving toward a regional laboratory system. On February 6, 2019, the Ministry met with the LHIN CEOs to encourage them to consider undertaking a costs and benefits analysis of moving to a network model. The Ministry will continue to work with the LHINs on the implementation of this recommendation while the transition to Ontario Health continues.

- *establish guidelines for hospitals to determine the test prices they charge to each other.*

Status: In the process of being implemented by December 2020.

Details

In our 2017 audit, we found that hospitals could send laboratory testing to other hospitals if their equipment was down or if they found that it was not cost-effective to do the tests themselves. However, the Ministry did not provide any guidelines to ensure fair and reasonable prices were being charged to other hospitals. Therefore, hospitals were using inconsistent billing practices when providing laboratory services on behalf of other hospitals.

In our follow-up, we found that the Ministry had been working with the LHINs to establish guidelines for hospitals to determine the test prices they charge to each other. On February 6, 2019, the Ministry met with the LHIN CEOs to encourage them to consider establishing guidelines for hospitals to determine the test prices they charge to each other. The Ministry will continue to work with the LHINs on the implementation of this recommendation while the transition to Ontario Health continues.

No Consistent Performance Monitoring of Laboratory Service Providers

Recommendation 10

To ensure that the laboratory sector in Ontario is operating effectively and efficiently as well as providing value and timely services to Ontarians, we recommend that the Ministry of Health and Long-Term Care:

- *establish standard performance targets and measures for community and hospital laboratories, collect and analyze performance information from laboratories, and take corrective action if targets are not met;*

Status: In the process of being implemented by December 2020.

Details

In our 2017 audit, we found that the Ministry did not set provincial performance targets or collect performance information to measure, monitor and determine whether laboratory services were provided efficiently and in a consistent and timely manner across Ontario.

In our follow-up, we found that the Ministry had worked with the community and hospital laboratories to establish performance targets and measures and collect performance information.

For community laboratories, the Ministry established 11 key performance indicators as part of its Transfer Payment Agreement with each community laboratory service provider. Examples of these indicators include patient wait time, laboratory turnaround time, blood culture contamination rate and specimen rejection rate. Failure to meet these key performance indicators may result in penalties. The Ministry has implemented eight of these 11 indicators. The three remaining indicators to be implemented are patient satisfaction, physician satisfaction, and Ontario laboratory information system data completeness. The Ministry will start taking corrective action once all indicators have been implemented by December 2020.

For hospital laboratories, on February 6, 2019, the Ministry met with the LHIN CEOs to encourage them to consider establishing standard performance targets and measures, collecting and analyzing performance information from laboratories, and taking corrective action if targets are not met. The Ministry will continue to work with the LHINs on the implementation of this recommendation while the transition to Ontario Health continues.

The Ministry will also work with Health Quality Ontario by December 2019 in order to determine the feasibility of establishing province-wide performance targets for hospital laboratories.

- *set wait-time targets for specimen collection in hospitals (for out-patients) and community specimen collection centres, regularly collect and*

assess wait times, and take corrective action if targets are not met.

Status: In the process of being implemented by December 2019.

Details

In our 2017 audit, we found that the Ministry did not set wait-time targets and did not collect wait-time information to measure and monitor the length of time that patients had to wait to have their specimens collected at hospital or community collection centres. Therefore, the Ministry did not know whether the laboratories collected specimens within a reasonable amount of time.

In our follow-up, we found that under the Transfer Payment Agreements with the Ministry, the community laboratories are required to meet the patient wait-time target, which measures the amount of time to see at least 90% of patients in any time period. Starting in April 2020, the Ministry will tighten this target by changing it from 35 minutes to 30 minutes and require the community laboratories to submit a patient wait-time report on a monthly basis.

The Ministry had an initial discussion about wait times in hospitals with LHIN CEOs in February 2019. The Ministry will continue to work with the LHINs on the implementation of this recommendation while the transition to Ontario Health continues. As mentioned above, the Ministry will also work with Health Quality Ontario by December 2019 to determine the feasibility of establishing province-wide performance targets for hospital laboratories.

Inadequate Oversight of Quality Management Program

Recommendation 11

To ensure that the quality management program provides useful information to identify where the quality of laboratory services needs improvement across the province, we recommend that the Ministry of Health and Long-Term Care obtain and analyze appropriate

accreditation and proficiency test results from the Institute for Quality Management in Healthcare on a regular basis and evaluate if any additional corrective action is warranted.

Status: Fully implemented.

Details

In our 2017 audit, we found that the Ministry did not collect useful information to assess the results of the Institute for Quality Management in Healthcare's (Institute) quality management program on an ongoing basis. The Institute's quarterly and annual reports to the Ministry contained limited, high-level summary information on the Institute's quality management activities (such as the number of site assessment visits done by the Institute) as opposed to detailed information on how individual laboratories were performing (such as the number of issues the Institute found during assessment visits of laboratories or proficiency testing).

In our follow-up, we found that under the existing agreement between the Ministry and the Institute, the Ministry requires the Institute to submit quarterly reports on accreditation activity and assessment visits; accountability of proficiency testing (to ensure that laboratory processes provide accurate test results); and financial activity. The Ministry also receives reports that flag issues relating to licensing infractions and non-compliance.

The Ministry has implemented a one-year extension agreement with the Institute. The agreement has quarterly reporting requirements in place. At the time of our follow-up, the Ministry was currently pursuing having the Institute continue providing its services.

Areas of Improvement for Quality Management Program

Recommendation 12

To ensure that Ontario's quality management program continues to operate effectively in assessing the quality and accuracy of laboratory services provided by all licensed laboratories and specimen collection

centres in Ontario, we recommend that the Ministry of Health and Long-Term Care conduct an analysis of similar programs in other jurisdictions to identify best practices that can be implemented in Ontario (such as implementing more rigorous accreditation standards and performing unannounced accreditation assessment site visits).

Status: Little or no progress.

Details

In our 2017 audit, we found that while Ontario had a quality management program in place through the Institute for Quality Management in Healthcare (Institute), improvements could be made. These included moving to a more rigorous accreditation standard and performing unannounced site visits.

In our follow-up, we found that the Ministry had not conducted an analysis of similar quality management programs in other jurisdictions to identify best practices. However, as part of its proposed four-year new agreement with the Institute (discussed in the action item above), the Ministry plans to include a provision to carry out a value assessment of the Institute's work. The Ministry is considering options on how it will undertake an external review of the Institute, which may include engaging an external consultant, as well as planning to undertake a jurisdictional analysis of laboratory quality management programs in other provinces.