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INDEPENDENT AUDITOR'S REPORT ON COMPLIANCE WITH REQUIREMENTS OF THE MEDICAID PROGRAM APPLICABLE TO SELECT LABORATORY SERVICES

Ohio Department of Medicaid 50 West Town Street, Suite 400 Columbus, Ohio 43215

RE: LabOne of Ohio, Inc. dba Quest Diagnostics

Ohio Medicaid Number: 2456695 National Provider Identifier: 1134165970

We examined compliance with specified Medicaid requirements for administration qualifications, service documentation, service authorization and coverage limitations related to the provision of select laboratory services during the period of January 1, 2022 through December 31, 2022 for LabOne of Ohio, Inc. dba Quest Diagnostics (Quest Diagnostics). We selected the following services:

- All instances in which a potential duplicate laboratory service was reimbursed (same recipient, procedure code, service date, modifiers, units and paid amount;
- All definitive drug tests involving 22 or more drug classes on a single date of service;
- All instances in which more than 12 definitive drug tests were reimbursed for the same recipient;
- All COVID-19 tests for the two outlier recipients (in terms of number of tests);
- A sample of laboratory services for the outlier recipient (in terms of reimbursements); and
- A sample of laboratory services ordered by the same ordering physician.

Quest Diagnostics entered into an agreement with the Ohio Department of Medicaid (the Department) to provide services to Medicaid recipients and to adhere to the terms of the provider agreement, Ohio Revised Code, Ohio Administrative Code, and federal statutes and rules, including the duty to maintain all records necessary and in such form so as to fully disclose the extent of services provided and significant business transactions. Management of Quest Diagnostics is responsible for its compliance with the specified requirements. The Compliance Section of this report identifies the specific requirements examined. Our responsibility is to express an opinion on Quest Diagnostics' compliance with the specified Medicaid requirements based on our examination.

Our examination was conducted in accordance with attestation standards established by the American Institute of Certified Public Accountants (AICPA). Those standards require that we plan and perform the examination to obtain reasonable assurance about whether Quest Diagnostics complied, in all material respects, with the specified requirements referenced above. We are required to be independent of Quest Diagnostics and to meet our ethical responsibilities, in accordance with the ethical requirements established by the AICPA related to our compliance examination.

An examination involves performing procedures to obtain evidence about whether Quest Diagnostic complied with the specified requirements. The nature, timing and extent of the procedures selected depend on our judgment, including an assessment of the risks of material noncompliance, whether due to fraud or error. We believe the evidence we obtained is sufficient and appropriate to provide a reasonable basis for our modified opinion. Our examination does not provide a legal determination on Quest Diagnostics' compliance with the specified requirements.

Internal Control over Compliance

Quest Diagnostics is responsible for establishing and maintaining effective internal control over compliance with the Medicaid requirements. We did not perform any test of the internal controls, and we did not rely on the internal controls in determining our examination procedures. Accordingly, we do not express an opinion on the effectiveness of the Quest Diagnostics' internal control over compliance.

Basis for Qualified Opinion

Our examination disclosed that, in a material number of instances, Quest Diagnostics did not obtain the required prior authorization to support the medical necessity of definitive drug tests exceeding Medicaid coverage limitation or for definitive drug tests for 22 or more drug classes in a single day.

Qualified Opinion on Compliance

In our opinion, except for the effects of the matters described in the Basis for Qualified Opinion paragraph, Quest Diagnostics has complied, in all material respects, with the select requirements of laboratory services for the period of January 1, 2022 through December 31, 2022.

Our testing was limited to the specified Medicaid requirements detailed in the Compliance Section. We did not test other requirements and, accordingly, we do not express an opinion on Quest Diagnostics' compliance with other requirements.

We identified improper Medicaid payments in the amount of \$3,886.98. This finding plus interest in the amount of \$592.63 (calculated as of March 3, 2025) totaling \$4,479.61 is due and payable to the Department upon its adoption and adjudication of this examination report. Services billed to and reimbursed by the Department, which are not validated in the records, are subject to recoupment through the audit process per Ohio Admin. Code 5160-1-27.

This report is intended solely for the information and use of Quest Diagnostics, the Department and other regulatory and oversight bodies, and is not intended to be, and should not be used by anyone other than these specified parties.

Keith Faber Auditor of State Columbus, Ohio

March 31, 2025

COMPLIANCE SECTION

Background

Title XIX of the Social Security Act, known as Medicaid, provides federal cost-sharing for each State's Medicaid program. The rules and regulations for the program are specified in the Ohio Administrative Code and the Ohio Revised Code. Medicaid providers must "maintain all records necessary and in such form so as to fully disclose the extent of services provided and significant business transactions" for a period of six years from receipt of payment or until any audit initiated within the six-year period is completed. Per Ohio Admin. Code 5160-1-17.2(D) and (E), providers must furnish such records for audit and review purposes.

Quest Diagnostics is an independent laboratory in Cincinnati, Ohio. Under the provider number examined, Quest Diagnostics received payment of over \$33.2 million for approximately 1.5 million laboratory services. LabOne of Ohio, Inc. was acquired by Quest Diagnostics in 2005 and does business as Quest Diagnostics which is a registered fictitious name with the Ohio Secretary of State. Quest Diagnostic has multiple locations throughout the country. The scope of this examination was limited to the Cincinnati, Ohio location.

Appendix I contains the laboratory services selected for this examination.

Purpose, Scope, and Methodology

The purpose of this examination was to determine whether Quest Diagnostics' claims for payment complied with Ohio Medicaid regulations. Please note that all rules and code sections relied upon in this report were those in effect during the examination period and may be different from those currently in effect. The scope of the engagement was limited to select laboratory services, as specified below, for which Quest Diagnostics billed with dates of service from January 1, 2022 through December 31, 2022 and received payment.

We obtained Quest Diagnostics' claims data from two Medicaid managed care entities (MCEs). We confirmed the services were paid to the Quest Diagnostics' tax identification number. We removed all services paid at zero, third-party payments, co-payments, duplicate payments, and Medicare crossover claims. The scope of our examination included testing procedures related to select services as identified in the Independent Auditor's Report.

The exception tests and calculated sample sizes are shown in **Table 1**.

Table 1: Exception Tests and Samples				
Universe	Population Size	Sample Size	Selected Services	
Exception Tests				
Potential Duplicates			82	
Definitive Drug Tests for 22 or More Drug Classes			5	
Recipients with More than 12 Definitive Drug Tests			33	
COVID-19 Testing Outliers			49	
Samples				
Outlier Recipient Laboratory Services	61 RDOS ²	10 RDOS	21	
Outlier Ordering Provider Laboratory Services	4,627 RDOS	60 RDOS	150	
Total			340	

¹ Payment data from the Medicaid claims database.

² An RDOS represents a recipient date of service which is defined as all services for a given recipient on a specific date of service.

Purpose, Scope, and Methodology (Continued)

A notification letter was sent to Quest Diagnostics setting forth the purpose and scope of the examination. During the entrance conference, Quest Diagnostics described its documentation practices and billing process. During fieldwork, we obtained an understanding of the electronic health record system used and reviewed service documentation. We sent preliminary results to Quest Diagnostics and it subsequently submitted additional documentation which we reviewed for compliance prior to the completion of our fieldwork.

Results

The summary results are shown in **Table 2**. The non-compliance and basis for findings is discussed below in further detail.

Table 2: Results						
Universe	Services Examined	Non- compliant Services	Non- compliance Errors	Improper Payment		
Exception Tests						
Potential Duplicates	82	1	1	\$30.94		
Definitive Drug Tests for 22 or More Drug Classes	5	5	5	\$731.50		
Recipients with More than 12 Definitive Drug Tests	33	33	33	\$3,124.54		
COVID-19 Testing Outliers	49	0	0	\$0		
Samples						
Outlier Recipient Laboratory Services	21	0	0	\$0		
Outlier Ordering Provider Laboratory Services	150	0	0	\$0		
Total	340	39	39	\$3,886.98		

A. Administration Qualifications

Per Ohio Admin. Code 5160-1-17.2(H), in signing the Medicaid provider agreement, a provider agrees that the individual practitioner or employee of the company is not currently subject to sanction under Medicare, Medicaid, or Title XX; or is otherwise prohibited from providing services to Medicaid beneficiaries.

We identified 22 administrative staff members and compared their names to the Office of Inspector General exclusion database and the Department's exclusion/suspension list and found no matches.

B. Service Documentation

Per Ohio Admin. Code 5160-11-11(C)(3)(d)(ii), a laboratory provider is to keep a copy of any clinical diagnostic procedure result for which consultation or interpretation was ordered. We obtained supporting documentation from Quest Diagnostics and confirmed there was a laboratory result to support the selected services with the exception noted below. We did not test service documentation requirements for those services as specified in the Medicaid Coverage section of this report.

Potential Duplicates Exception Test

The 82 services examined contained was one instance in which a duplicate service was billed. This error resulted in an improper payment amount of \$30.94.

Recommendation

Quest Diagnostics should develop and implement procedures to ensure that billing practices fully comply with the requirements contained in the Ohio Medicaid rules. Quest Diagnostics should address the identified issue to ensure compliance with the Medicaid rules and avoid future findings.

C. Authorization to Provide Services

In accordance with Ohio Admin. Code 5160-11-11(C)(3), a laboratory provider may submit a claim only after it has obtained a written order. A written order includes, but is not limited to, contact information for the practitioner ordering the service, the date or the order, and the specification of the service. We obtained written orders from Quest Diagnostics and confirmed there was a written order to support the selected services. We did not test service authorization requirements for those services as specified in the Medicaid Coverage section of this report.

D. Medicaid Coverage

Per Ohio Admin. Code 5160-11-11(C)(5)(f), a laboratory provider must obtain prior authorization for definitive drug tests involving 22 or more drug classes on a single date of service as well as definitive drug tests exceeding 12 dates of service per calendar year. We confirmed with the two MCEs that it imposed the same limitation. We requested support for prior authorization from Quest Diagnostics for the specified services below.

Definitive Drug Tests for 22 or More Drug Classes Exception Test

There was no prior authorization to support the medical necessity for the five services examined. These five errors resulted in the improper payment amount of \$731.50.

Recipients with More than 12 Definitive Drug Tests Exception Test

There was no prior authorization to support the medical necessity for the 33 services examined. These 33 errors resulted in the improper payment amount of \$3,124.54.

Recommendation

Quest Diagnostics should ensure that services billed to Medicaid are consistent with coverage and limitations contained in the Ohio Admin. Code. Quest Diagnostics should address the identified issue to ensure compliance with Medicaid rules and avoid future findings.

Official Response

Quest Diagnostics submitted an official response to the results of this examination which is presented in **Appendix II**. We did not examine Quest Diagnostics' response, and, accordingly, we express no opinion on it.

APPENDIX I

Laboratory Services				
Procedure Code	Description			
36415	Blood Collection by Needle Insertion			
80053	Comprehensive Metabolic Panel			
80074	Hepatitis Panel			
80307	Presumptive Drug Test, Any Number of Drug Classes			
81025	Urine Pregnancy Test			
81513	Bacterial Vaginosis Screening			
82248	Bilirubin Levels			
83519	Analytes Identification Using Radioimmunoassay			
83520	Analytes Identification Using Quantitative Analysis			
85025	Complete Blood Count with Automated Differential of White Blood Cells			
85027	Automated Complete Blood Count			
86146	Beta-2 Glycoprotein 1 Antibody, Each			
86255	Noninfectious Antibody Using Fluorescent Technique, Each			
86341	Detection of Islet Cell Antibodies			
86592	Syphilis Screening			
86704	Hepatitis B Core Screening			
86706	Hepatitis B Surface Screening			
86708	Hepatitis A Screening			
86803	Hepatitis C Screening			
87076	Definitive Identification of Anaerobic/Aerobic Culture			
87177	Ova And Parasite Identification via Stool Sample			
87209	Ova And Parasite Identification Using Complex Special Stain			
87340	Hepatitis B Surface Antigen Screening			
87389	HIV-1 And HIV-2 Screening			
87449	Detection of Each Infectious Agent			
87491	Chlamydia Screening			
87522	Detection of Hepatitis C Infectious Agents			
87591	Gonorrhoeae Screening			
87624	Human Papillomavirus (HPV) Screening			
87661	Trichomonas Vaginalis Screening			
87798	Detection of Infectious Agents			
87799	Quantification of Infectious Agents			
87801	Detection of Multiple Infectious Agents			
88142	Vaginal Cytopathology (PAP Test)			
G0480	Definitive Drug Test, 1-7 Drug Classes			
G0481	Definitive Drug Test, 8-14 Drug Classes			
G0482	Definitive Drug Test, 15-21 Drug Classes			
G0483	Definitive Drug Test, 22 or More Drug Classes			
U0003	COVID-19 Screening			

Source: Current Procedural Terminology manual

APPENDIX II



Keith Faber, Auditor of State and Michael Schmidt, Chief Auditor 65 East State Street, 14th Floor Columbus, Ohio 43215

RE: LabOne of Ohio, Inc. dba Quest Diagnostics

Ohio Medicaid Number: 2456695 National Provider Identifier: 1134165970

April 10, 2025

To Whom It May Concern:

This letter is being sent in response to the Medicaid compliance examination report received by Quest Diagnostics (Quest) on March 20, 2025.

With regard to the report findings of: **Definitive Drug Tests for 22 or More Drug Classes (5 findings) and Recipients with More than 12 Definitive Drug Tests (33 findings)**, Quest will continue to educate providers identified in the audit regarding the Ohio Medicaid Guidelines for Urine Drug Screen Utilization.

When requesting prior authorization documentation from the ordering providers as part of this audit, numerous providers informed Quest that no prior authorization was required for the testing in question. Written communication from these providers was sent to the Auditor of State in response to the prior authorization request. Based on these responses, Quest would like to respectfully request that the Ohio Department of Medicaid also re-issue Urine Drug Screen Utilization Guidelines to its participating providers and remind providers of prior authorization requirements and coverage limitations.

To further support your coverage guidelines, Quest can operationalize limiting billing to up to 12 definitive drug classes per test requisition order. Please confirm that you wish for us to proceed with this approach.

Quest Diagnostics values its relationship with Ohio Medicaid and looks forward to resolving this audit in a timely and amicable manner. Toward that end, please feel free to contact me should you have any questions regarding this letter.

Kind Regards,

Casey Hoppe

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LABONE OF OHIO, INC. DBA QUEST DIAGNOSTICS HAMILTON COUNTY

AUDITOR OF STATE OF OHIO CERTIFICATION

This is a true and correct copy of the report, which is required to be filed pursuant to Section 117.26, Revised Code, and which is filed in the Office of the Ohio Auditor of State in Columbus, Ohio.



Certified for Release 4/22/2025

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