

MATERIAL CHANGE NOTICE SUBMISSION DETAILS

MCN Number	2025-03-12-1360
OHCA Review Start Date	May 28, 2025
Anticipated date (unless tolled per regulation) by which OHCA could waive cost and market impact review	July 14, 2025
Anticipated date (unless tolled per regulation) by which OHCA could determine cost and market impact review required	July 28, 2025

SUBMITTER

HEALTH CARE ENTITY CONTACT FOR PUBLIC INQUIRY

Title	Ms.
First Name	Jessica
Last Name	Hanna
Email Address	jessica.hanna@hoganlovells.com

GENERAL

Business Name	Fresenius Medical Care Holdings, Inc.
Website	https://freseniusmedicalcare.com/en-us/
Ownership Type	Corporation
Tax Status	For-profit
Federal Tax ID	13-3461988
Description of Submitting Organization	<p>Submitter is the leading provider of products and services for individuals with renal diseases. Submitter offers products and services along the entire dialysis value chain from a single source. As of December 31, 2023, Submitter cared for more than 332,000 patients in its global network of roughly 4,000 dialysis clinics. At the same time, Submitter operated around 40 production sites on all continents, to provide dialysis products such as dialysis machines, dialyzers and related disposables. Submitter aims to continuously improve its patients' quality of life by offering them high-quality products as well as innovative technologies and treatment concepts.</p> <p>Submitter's corporate headquarters are located in Bad Homburg v. d. Höhe, Germany. The North American regional offices are located in Waltham, Massachusetts. Submitter is a New York corporation.</p> <p>Business lines or segments: (1) Health care</p>

	<p>products, focusing on hemodialysis, peritoneal dialysis, and acute dialysis products; and (2) Health care services, including dialysis services and other health care services.</p> <p>Fresenius Medical Care Holdings, Inc. is a subsidiary of Fresenius Medical Care AG, a public limited company formed under the laws of Germany (the ultimate parent). Spectra Laboratories, Inc. and Spectra East, Inc., are both subsidiaries of Fresenius Medical Care Holdings, Inc., as shown in greater detail in the organizational charts attached.</p> <p>Fresenius Medical Care Holdings, Inc. 2024 CA Revenue: \$1.3B 2023: \$1.3B 2022: \$1.2B</p>
Health Care Provider	Yes
For Providers: Desc. of Capacity or Patients served in California	<p>The Submitter is the world's leading provider of products and services for individuals with kidney diseases. Submitter provides dialysis and related services for individuals with renal diseases as well as other health care services, including pharmacy services, vascular, cardiovascular, and endovascular specialty services, ambulatory surgery center services, and physician nephrology and cardiology services. Submitter also develops, manufactures, and distributes a wide variety of health care products, including hemodialysis machines and peritoneal dialysis cyclers, dialyzers, bloodlines, systems for water treatment.</p> <p>Submitter owns and operates healthcare facilities all around the world, including many locations in California. A list of Submitter's California facilities is attached. These facilities are not affected by the transaction.</p> <p>Submitter provides dialysis services in all counties in California. Patient count by California county is attached.</p> <p>Submitter has approximately 4,500 employees in California.</p>

LOCATIONS

Counties	All Counties; Alameda; Alpine; Amador; Butte; Calaveras; Colusa; Contra Costa; Del Norte; El Dorado; Fresno; Glenn; Humboldt; Imperial; Inyo; Kern; Kings; Lake; Lassen; Los Angeles; Madera; Marin; Mariposa; Mendocino; Merced; Modoc; Mono; Monterey; Napa; Nevada; Orange; Placer; Plumas; Riverside; Sacramento; San Benito; San Bernardino; San Diego; San Francisco; San Joaquin; San Luis Obispo; San Mateo; Santa Barbara; Santa Clara; Santa Cruz; Shasta; Sierra; Siskiyou; Solano; Sonoma; Stanislaus; Sutter; Tehama; Trinity; Tulare; Tuolumne; Ventura; Yolo; Yuba
California licenses and numbers	No facilities are involved in the transaction.
Other States Served	None; AK; AL; AR; AZ; CO; CT; DC; DE; FL; GA; HI; IA; ID; IL; IN; KS; KY; LA; MA; MD; ME; MI; MN; MO; MS; MT; NC; ND; NE; NH; NJ; NM; NV; NY; OH; OK; OR; PA; RI; SC; SD; TN; TX; UT; VA; VT; WA; WI; WV; WY
Other state(s) licenses and numbers	Submitter holds licenses in other states but none are involved in or affected by this transaction.
Primary Languages used when providing services	English
Other language if not listed above	

MATERIAL CHANGE

ADDITIONAL ENTITIES

Business Name	Description of the Organization	Ownership Type	Additional MCN Submission
Quest Diagnostics Incorporated	Revenue in California for the past three years: 2022: \$1,180,240,263; 2023 \$1,083,213,464; 2024: \$1,098,887,814	Corporation	Yes

CRITERIA

A health care entity with annual revenue, as defined in section 97435(d) , of at least \$25 million or that owns or controls California assets of at least \$25 million, or;	Yes
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A health care entity with annual revenue, as defined in section 97435(d) , of at least \$10 million or that owns or controls California assets of at least \$10 million and is a party to a transaction with any health care entity satisfying subsection (b)(1), or	Yes
A health care entity located in a designated primary care health professional shortage area in California, as defined in Part 5 of Subchapter A of Chapter 1 of Title 42 of the Code of Federal Regulations (commencing with section 5.1), available at data.hrsa.gov . To determine if you are located in a primary health care professional shortage area, please visit here	No

CIRCUMSTANCES FOR FILING

The proposed fair market value of the transaction is \$25 million or more and the transaction concerns the provision of health care services.	Yes
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TRANSACTION DETAILS

Anticipated Date of Transaction Closure	6/30/2025
Description of the Transaction	<p>The transaction is an asset sale, through which Quest Diagnostics will acquire certain Spectra Laboratories, Inc. and Spectra East, Inc. ("Spectra") assets from Fresenius Medical Care Holdings, Inc. in accordance with the terms of the negotiated Asset Purchase Agreement. Quest will acquire Spectra's laboratory services business providing dialysis and environmental and water testing services to external customers. The acquired assets include certain contracts, inventory, equipment and supplies.</p> <p>The transaction is expected to provide patients, physicians and external customers with greater access to Quest's comprehensive, high-quality laboratory services, scientific expertise and expanded testing capabilities in key regions across the United States. The transaction will increase access to a wide range of renal lab services, such as chemistry, hematology, microbiology and trace element testing. The transaction will have a positive public impact as Quest will be better positioned to provide patients and providers with superior levels of service quality and robust testing offerings.</p> <p>The parties do not anticipate that the transaction will have any adverse impact to the public.</p>

Submitted to US Department of Justice or Federal Trade Commission?	No
Submitted to Other Agency?	Yes
Date of Submission	2/27/2025
To Whom Submitted	Indiana Attorney General
Description of Submission (Include Agency name(s) and State(s))	Notice of Healthcare Transaction submitted to the Indiana Office of Attorney General pursuant to Indiana's material health care transaction reporting statute.
Subject to court proceeding	No
Description of current services provided and expected post-transaction impacts on health care services	<p>Quest Diagnostics provides laboratory testing services to patients across the U.S. and does not anticipate any changes to these services as a result of the transaction.</p> <p>Services are currently provided in all California counties. No changes to the counties where services are performed are expected.</p> <p>There will be no changes to levels and types of health care services offered.</p> <p>There will be no changes to the number or type of patients served.</p> <p>There will be no changes to community needs assessments, charity care, and community benefit programs.</p> <p>There will be no changes to whether Medi-Cal and Medicare patients are accepted.</p>
Prior mergers or acquisitions that: (A) involved the same or related health care services; (B) involved at least one of the entities, or their parents, subsidiaries, predecessors, or successors, in the proposed transaction; and (C) were closed in the last ten years.	None to report.
Description of Potential Post Transaction Changes	<p>Submitter does not anticipate making any ownership, governance, or operational changes post-transaction. Quest Diagnostics does not currently anticipate making any ownership, governance, or operational structure changes related to the Spectra assets post-closing.</p> <p>No changes to staffing, job security, retraining policies, wages, benefits, working conditions, and/or employment protections are expected.</p> <p>Quest Diagnostics does not currently anticipate making any changes to city or county contracts, if any, regarding the provision of health care services that are</p>

	related to the Spectra's assets post-closing. The parties are unaware of any potential post-transaction changes to comparable health services offered by other health care entities within 20 miles of any location in which either party offers health care services.
Description of the nature, scope, and dates of any pending or planned material changes occurring between the Submitter and any other entity, within the 12 months following the date of the notice	None.

April 2, 2025

Kristen Colburn
Attorney, Office of Health Care Affordability
2020 West El Camino Avenue, Suite 800
Sacramento, CA 95833

Dear Ms. Colburn,

On behalf of Fresenius Medical Care Holdings, Inc. (“Fresenius”), I am writing in response to your March 17 letter regarding Material Change Notice Submission 2025-03-12-1360. Below, we address each of your requests in turn.

1. Information Regarding Spectra East, Inc. and Spectra Laboratories, Inc.

Spectra East, Inc. and Spectra Laboratories, Inc. (collectively, “Spectra Laboratories”) is dedicated to providing comprehensive diagnostic testing services for renal patients and their healthcare partners. Spectra Laboratories performs more than 78 million tests each year, including chemistry, hematology, anemia therapy testing, immunochemistry, peritoneal dialysis adequacy testing, prothrombin time, serology, aluminum, I-PTH, Vitamin D, therapeutic drug monitoring, water and dialysate testing, hepatitis and confirmatory tests, and testing for acute patients. Spectra Laboratories also provides dialysis calculations for quality assessment of therapy, including urea reduction rate, kinetics (quick, Daugirdas, and full UKM), and peritoneal equilibration testing. These tests allow health care teams to understand how effective dialysis treatments are, if patients are on the right level of medications, and can even help to identify nutritional needs.

In addition to providing testing services, Spectra Laboratories also provides clinical education to health care providers and patients, including on proper specimen collection, preparation, and handling, and on Spectra Laboratories’ ordering, reporting, and data management application. Spectra Laboratories also provides customer support, and specimen transport services.

Organizational charts for both Spectra East, Inc. and Spectra Laboratories, Inc. were submitted with the original MCN Notice, showing that both entities are subsidiaries of Fresenius.

Spectra Laboratories does not have a physical location in the state of California. Spectra Laboratories patients may have their samples routed to either of Spectra Laboratories physical laboratory locations, located at: (1) 8 King Road, Rockleigh, NJ 07647; and (2) 1280 Stateline Road East, Southaven MS 38671. Generally, samples from patients residing in California would

be routed to the Mississippi laboratory for testing. Spectra Laboratories accepts patient samples from patients residing in all California counties.

Spectra Laboratories has six employees in the state of California.

Spectra Laboratories served 18,565 total California patients in 2024. 1,960 of those patients relate to the in-scope assets being transferred to Quest as a result of the transaction.

Spectra East, Inc. (which owns the New Jersey laboratory, which generally does not receive California samples) had \$0 in California revenue associated with the in-scope assets that are being transferred to Quest as part of the proposed transaction over the past three years¹. This is largely because as mentioned above, California patient samples are routed to the Mississippi laboratory, which is owned by Spectra Laboratories, Inc.

Spectra Laboratories, Inc.’s California revenue associated with the in-scope assets for the past three years is shown below.

2022: \$2,210,084

2023: \$1,570,738

2024: \$1,706,420

Spectra Laboratories’ primary language is English. Spectra complies with applicable law regarding providing services to those with limited English proficiency.

The following chart shows the licenses and accreditations held by Spectra Laboratories:

Entity	License or Accreditation
Spectra East, Inc.	College of American Pathologists (“CAP”) Certificate of Accreditation #1204501
	Clinical Laboratory Improvement Amendments (“CLIA”) Accreditation, ID 31D0961672
	California Department of Public Health (“CA DPH”), Clinical and Public Health Laboratory License, ID CDS-00800091
	New Jersey Department of Health, Clinical Laboratory License, CLIS ID 0001348
	New York State Department of Health (“NY DOH”), Clinical Laboratory Permit, Serial: LAP 18806

¹ With the exception of \$1,200 revenue in 2023, due to an allocation nuance.

	NY DOH Certificate of Approval for Laboratory Service – Environmental Analyses Potable Water ID No. 11687
	Maryland Department of Health (“MD DOH”), Medical Laboratory Permit No. 618
	Pennsylvania Department of Health (“PA DOH”) Clinical Laboratory Permit No. 21307A
	Rhode Island Department of Health (“RI DOH”) – Out of State Clinical Laboratory License No. LCO00202
Spectra Laboratories, Inc.	CAP Certificate of Accreditation #9102117
	CLIA Accreditation, ID 25D2227753
	CA DPH Clinical and Public Health Laboratory License, ID CDS-90005032
	NY DOH Clinical Laboratory Permit, Serial LAP 174046
	NY DOH Certificate of Approval for Laboratory Service – Environmental Analyses Potable Water ID No. 12151
	MD DOH Medical Laboratory Permit No. 3549
	PA DOH Clinical Laboratory Permit No. 39748
	RI DOH Out of State Clinical Laboratory License No. LCO01493

2. Information Regarding Quest Diagnostics (“Quest”)

Please refer to Quest’s MCN Submission Number 2025-02-28-1318, and Quest’s responses to OCHA’s letter requesting additional information dated March 17, 2025.

3. Description of Current Services Provided by Fresenius and Post-Transaction Changes

There will be no changes to the services provided by Fresenius post-transaction. For the Spectra Laboratories assets that are being transferred to Quest, Quest will continue to provide the same comprehensive diagnostic testing services for renal patients post-transaction. The parties do not expect that there will be any net decrease in the availability of services to patients in the state of California as a result of the transaction.

More specifically:

(A) Spectra Laboratories currently accepts samples from all California counties, and expects that Quest will consider to do so for the in-scope assets that will be transferred as a result of the transaction post-close.

(B) Spectra Laboratories currently provides a full slate of comprehensive diagnostic testing services for renal patients, and expects that Quest Diagnostics will continue to provide those services (with respect to the in-scope assets that are transferring as a result of the transaction) post-transaction.

(C) Spectra Laboratories currently provides services to patients regardless of age, gender, race, ethnicity, preferred language, disability status, and payer category. We expect no change to that as a result of the transaction.

(D) Fresenius offers patient financial assistance to patients who qualify for it, based upon the patient's completion of an application for financial assistance and the provision of supporting documentation. Post-transaction, with respect to the in-scope assets that are transferring as a result of the transaction, patients will have access to Quest Diagnostics' patient financial assistance programs.

(E) Spectra Laboratories currently accepts samples from Medi-Cal and Medicare patients, and expects that Quest Diagnostics will continue to do so with respect to the in-scope assets that are transferring as a result of the transaction post-close.

* * *

I authorize OHCA to amend my submission on my behalf (and on behalf of Fresenius) to include the additional information set forth above, as requested by OHCA in its letter dated March 17, 2025. I certify under penalty of perjury under the laws of the State of California that the information and documents provided in the foregoing Material Change Notice are true and correct.

Please let us know if you have any questions or if there is anything further we can provide.

Many thanks,

Jessica Hanna