



Medicare Pharmacies and Other Suppliers May Temporarily Enroll as Independent Clinical Diagnostic Laboratories to Help Address COVID-19 Testing

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PROVIDER TYPES AFFECTED

This MLN Matters Article is for Medicare-enrolled pharmacies and other Medicare-enrolled suppliers, or pharmacies and suppliers seeking to enroll temporarily as independent clinical diagnostic laboratories to help address the urgent need for COVID-19 testing.

WHAT YOU NEED TO KNOW

Pharmacies and other suppliers currently enrolled in Medicare may also enroll temporarily as independent clinical diagnostic laboratories during the COVID-19 public health emergency via the provider enrollment hotline. This will provide additional laboratory resources to meet the urgent need to increase COVID-19 testing capability.

Pharmacies and other suppliers who are not currently enrolled in Medicare and want to enroll as an Independent Clinical Diagnostic Laboratory, must submit a [CMS-855B](#) enrollment application to the Medicare Administrative Contractor (MAC) serving your geographic area. To locate your designated MAC, see <https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/MACs-by-State-June-2019.pdf>.

ENROLLMENT GUIDANCE

Medicare-enrolled pharmacies and other Medicare-enrolled suppliers can initiate temporary Medicare independent clinical diagnostic laboratory billing privileges via the provider enrollment hotline (**see hotline information below**). To start the process, you will need to provide limited information, including:

- Legal Business Name
- National Provider Identifier (NPI)
- Tax Identification Number (TIN)

- State license
- CLIA certificate number (**see below**)
- Address information
- Contact information (telephone number).

Your MAC will collect this information from you over the phone, however, temporary Medicare billing privileges will not be established during the phone conversation. The MAC will notify the pharmacy or other supplier of their temporary Medicare billing privileges and effective date via email within 2 business days.

To maintain billing privileges as an Independent Clinical Diagnostic Laboratory, the pharmacy or other supplier must submit a [CMS-855B](#) enrollment application within 30 days after the public health emergency ends to the MAC serving your geographic area.

Provider Enrollment Hotline Information

Medicare-enrolled pharmacies and other Medicare-enrolled suppliers seeking to initiate temporary Medicare independent clinical diagnostic laboratory billing privileges should only contact the hotline for the MAC serving your geographic area. To locate your designated MAC see <https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/MACs-by-State-June-2019.pdf>.

The hotlines are operational Monday – Friday and at the specified times below.

CGS Administrators, LLC (CGS)

- The toll-free Hotline Telephone Number: 1-855-769-9920
- Hours of Operation: 7:00 am – 4:00 pm CT

First Coast Service Options Inc. (FCSO)

- The toll-free Hotline Telephone Number: 1-855-247-8428
- Hours of Operation: 8:30 AM – 4:00 PM EST

National Government Services (NGS)

- The toll-free Hotline Telephone Number: 1-888-802-3898
- Hours of Operation: 8:00 am – 4:00 pm CT

National Supplier Clearinghouse (NSC)

- The toll-free Hotline Telephone Number: 1-866-238-9652
- Hours of Operation: 9:00 AM – 5:00 PM ET

Novitas Solutions, Inc.

- The toll-free Hotline Telephone Number: 1-855-247-8428
- Hours of Operation: 8:30 AM – 4:00 PM EST

Noridian Healthcare Solutions

- The toll-free Hotline Telephone Number: 1-866-575-4067
- Hours of Operation: 8:00 am – 6:00 pm CT

Palmetto GBA

- The toll-free Hotline Telephone Number: 1-833-820-6138
- Hours of Operation: 8:30 am – 5:00 pm ET

Wisconsin Physician Services (WPS)

- The toll-free Hotline Telephone Number: 1-844-209-2567
- Hours of Operation: 7:00 am – 4:00 pm CT

Important Clinical Laboratory Improvement Amendments (CLIA) Certificate Number Information

Note that the CLIA program does not allow the Centers for Medicare & Medicaid Services (CMS) to approve section 1135 waiver requests with respect to waivers of CLIA program requirements for public health emergencies. The section 1135 waiver authority is only applicable to specified programs (or penalties) authorized by the Social Security Act (SSA). The CLIA program does not fall into this category of programs. CMS does not have the authority to grant waivers or exceptions that are not established in statute or regulation.

If you would like to apply for a CLIA certificate, please submit your application form ([CMS-116, CLIA Application Form](#)) to the state ([SA Contacts](#)) where the laboratory is located.

CMS wants to ensure that laboratories located in the United States applying for a CLIA certificate are able to begin testing for COVID-19 as quickly as possible. Once the laboratory has identified a qualified laboratory director and has provided all required information on the CMS-116 application, a CLIA number will be assigned. Once the CLIA number has been assigned, the laboratory can begin testing as long as applicable CLIA requirements have been met (for example, establishing performance specifications).

Note that different CLIA program certificates correspond to the complexity of tests performed by a given laboratory. For example, laboratories with a Certificate of Waiver can only conduct tests designated as waived by the Food and Drug Administration (FDA). More information is available at <https://www.cms.gov/Regulations-and->

[Guidance/Legislation/CLIA/Downloads/HowObtainCLIACertificate.pdf](#)

Information specific to obtaining a CLIA Certificate of Waiver is available at <https://www.cms.gov/Regulations-and-Guidance/legislation/CLIA/downloads/howobtaincertificateofwaiver.pdf>.

ADDITIONAL INFORMATION

Frequently Asked Questions (FAQs) about CLIA guidance during the COVID-19 emergency are available at <https://www.cms.gov/files/document/clia-laboratory-covid-19-emergency-frequently-asked-questions.pdf>.

CLIA laboratory guidance to state agencies during the COVID-19 Public Health Emergency are available at <https://www.cms.gov/files/document/qso-20-21-clia.pdf-0>.

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

DOCUMENT HISTORY

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May 8, 2020	Initial article released.

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