

NCPA Member Summary of CMS Rules Regarding Pharmacists Ability to Provide COVID-19 Testing

Please see updates made to this summary on 5/20/20 in red text below.

On April 30, 2020 CMS announced a second [interim final rule](#) with comment period (IFC) regarding Medicare and Medicaid policy and regulatory revisions in response to the COVID-19 public health emergency (PHE). Further, on May 8, 2020, CMS released an [MLN Matters Article](#) stating that **Medicare pharmacies may temporarily enroll as an Independent Clinical Laboratory** to help address COVID-19 testing. **Below is NCPA's current interpretation of the IFC as it applies to community and long-term care (LTC) pharmacies. NCPA is seeking further clarity from CMS on the below provisions and will update this document accordingly.**

NCPA advocacy at work for you

NCPA, along with the pharmacy industry, successfully [advocated](#) that CMS issue additional guidance regarding implementation of the [HHS Pharmacist Testing Guidance](#) with the goal of clarifying **access and payment under Medicare and Medicaid.**

NCPA successfully [advocated](#) that the Administration use pharmacists to **provide COVID-19 tests and testing site access for COVID-19.**

Pharmacists' ability to perform COVID-19 diagnostic testing (including serological and antibody tests)¹ under Medicare:

- Medicare will cover certain COVID-19 tests performed by pharmacists if they are **enrolled in Medicare as an Independent Clinical Laboratory (see next steps on page 3 for enrollment process)**, in accordance with scope of practice and state laws. With these changes, beneficiaries can get tested at "parking lot" test sites operated by pharmacies consistent with state requirements.
- Medicare may cover COVID-19 diagnostic tests when **ordered by any healthcare professional, authorized to do so under state law, including pharmacists.**² This applies to **influenza and respiratory syncytial virus (RSV) tests** as well when ordered in conjunction with a COVID-19 diagnostic test.³

¹ Medicare will cover FDA authorized COVID-19 serology tests, as they fall under the Medicare benefit category of diagnostic laboratory test (section 1861(s)(3) of the Act).

² CMS amends § 410.32(a) to remove the requirement that certain diagnostic tests are covered only based on the order of a treating physician or non-physician practitioner (NPP). **CMS states that most FDA-authorized tests and some states have an ordering requirement, and advises pharmacies to verify those requirements, but the order requirement will not be a factor for Medicare payment.**

³ CMS will make publicly available a list of diagnostic laboratory tests for which it is removing the ordering requirements when they are furnished in conjunction with a COVID-19 diagnostic laboratory test. CMS states no order is required, but it expects "the entity submitting the claim to include the ordering or referring NPI information on the claim form when an order is written for the test, consistent with current billing instructions."

- Medicare Part B covers clinical diagnostic laboratory tests, including COVID-19 diagnostic tests, **under the Clinical Laboratory Fee Schedule (CLFS)**, without any beneficiary cost-sharing requirements.
- When COVID-19 tests are furnished without a physician’s or non-physician practitioner (NPP)’s order during the COVID-19 PHE, **the laboratory** conducting the tests **is required to directly notify the patient of the results.**
- There are **two scenarios** where pharmacists can **conduct specimen collection in addition to providing the test:**
 - Pharmacists can work with a physician or other practitioner to **provide assessment and specimen collection services**, and the physician or other practitioner can bill Medicare for the services under “incident to” billing.
 - Pharmacists enrolled as an Independent Clinical Laboratory can either 1) go to patient’s home and collect a specimen (G2023), or 2) go to a skilled nursing facility to collect the patient’s specimen (G2024).
 - **Note, there is no scenario under which a pharmacist can bill for specimen collection performed for a patient in his/her own pharmacy.**
 - Pharmacists could also partner with a **lab** and perform the specimen collection on the lab’s behalf, but Medicare would not pay any additional amount to the pharmacy. This would be a strict business arrangement between the lab and the pharmacy. *(updated 5/20/20)*
 - These scenarios apply to influenza and RSV tests as well; however, there are currently only specimen collection codes available for COVID-19 tests.

Pharmacists’ ability to provide medication management services under Medicare Part B:

- Medicare Part B and Part D cover medication management.
- Under Part B, pharmacists are considered “auxiliary personnel” and, under the appropriate level of supervision, **may provide medication management services “incident to”** the services of the billing physician or NPP, **if payment is not made under the Part D benefit.**⁴ Such services may include medication management of individuals with substance/opioid use disorder, disease management, and any other clinical services as long as “incident to” requirements⁵ are met.
- Under Part D, **pharmacists may furnish medication management services under a Medication Therapy Management Program (MTMP)**, which is a program each Part D sponsor is required to incorporate into their plans’ benefit structure.⁶ MTMPs target Part D enrollees who have multiple chronic diseases and are taking multiple Part D drugs and must include interventions for beneficiaries and prescribers; an annual comprehensive medication review; and quarterly targeted medication reviews.

⁴ See § 410.26. Services must be in accordance with the pharmacist’s state scope of practice and applicable law. This clarification does not alter current payment policy for pharmacist services furnished incident to the services of the billing physician or NPP.

⁵ See § 410.26(b), available at <https://www.law.cornell.edu/cfr/text/42/410.26>.

⁶ See § 423.153(d).

Pharmacists' ability to perform COVID-19 testing under Medicaid:

- **Medicaid may cover COVID-19 tests**, including tests administered in non-office settings (such as parking lots or other temporary outdoor locations), and laboratory processing of self-collected COVID-19 tests that are FDA-authorized for self-collection.⁷
- The flexibility **would apply** not only during the current COVID-19 PHE, but also **during any subsequent periods of active surveillance** to detect recurrence of the virus.
- Pharmacists should work with their state partners to ensure Medicaid coverage of pharmacist administered COVID-19 tests.

Telehealth Expansion under Medicare:

- CMS is expanding its list of eligible clinical practitioners that can furnish Medicare telehealth services to include physical therapists, occupational therapists, and speech language pathologists. Prior to this change, only doctors, nurse practitioners, physician assistants, and certain others could deliver telehealth services.⁸
- **Standalone accredited diabetes self-management training (DSMT) programs that are unaffiliated with hospital and physician clinics, such as pharmacies, can provide telehealth services to new or established beneficiaries.**

Next Steps for NCPA members:

- Pharmacies **currently enrolled in Medicare** may also **enroll temporarily as an Independent Clinical Laboratory** during the COVID-19 PHE. **For pharmacies who already have a PTAN, you will get an additional PTAN.** To start, provide the below information to your [designated Medicare Administrative Contractor](#) (MAC) via the **provider enrollment hotline** (see table below for contact information). Your MAC will then notify you of your temporary Medicare billing privileges and effective date via email within 2 business days.
 - Legal Business Name
 - National Provider Identifier (NPI)
 - Tax Identification Number (TIN)
 - State license
 - CLIA certificate number
 - **To obtain a CLIA Certificate of Waiver**, submit an application form ([CMS-116, CLIA Application Form](#)) to the state ([SA Contacts](#)) where the laboratory is located. Once the CLIA number has been assigned, the laboratory can begin testing as long as applicable CLIA requirements have been met. 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 FDA. **NCPA has made a [short video](#)** to show you how a pharmacy would likely want to complete the form..
 - Address information
 - Contact information (telephone number)

⁷ See § 440.30.

⁸ See Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19, CMS, available at <https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf>.

| MAC | Toll-free Hotline Telephone Number | Hours of Operation |
|---|------------------------------------|-----------------------|
| CGS Administrators, LLC (CGS) | 1-855-769-9920 | 7:00 am – 4:00 pm CT |
| First Coast Service Options Inc. (FCSO) | 1-855-247-8428 | 8:30 am – 4:00 pm EST |
| National Government Services (NGS) | 1-888-802-3898 | 8:00 am – 4:00 pm CT |
| National Supplier Clearinghouse (NSC) | 1-866-238-9652 | 9:00 am – 5:00 pm ET |
| Novitas Solutions, Inc. | 1-855-247-8428 | 8:30 am – 4:00 pm EST |
| Noridian Healthcare Solutions | 1-866-575-4067 | 8:00 am – 6:00 pm CT |
| Palmetto GBA | 1-833-820-6138 | 8:30 am – 5:00 pm ET |
| Wisconsin Physician Services (WPS) | 1-844-209-2567 | 7:00 am – 4:00 pm CT |

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

- Pharmacies **who are not currently enrolled in Medicare and want to enroll as an Independent Clinical Laboratory must submit a CMS-855B enrollment application to the MAC** serving your geographic area (check [here](#) to locate your designated MAC). **Select “Independent Clinical Lab” on this form.**

Last updated: 5/20/20