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News

CMS Takes Action to Protect Integrity of COVID-19 Testing

CMS is taking every action to ensure U.S. laboratories are fit to deliver reliable, accurate, and timely patient test results for COVID-19 by confirming Clinical Laboratory Improvement Amendments of 1988 (CLIA) certifications are up-to-date. A recent record check by CMS resulted in the issuance of 171 cease and desist letters to facilities that did not have proper CLIA certifications in place. CLIA certification is important because it verifies that laboratories meet federal performance, quality, and safety standards to properly diagnose, prevent, and treat diseases.

"Testing capacity has rightly been at the top of President Trump's priority list since the early stages of this pandemic," said CMS Administrator Seema Verma. "But we also understood that for testing to fulfill its potential, tests must be reliable. Today's announcement will help ensure that Americans can rest secure that they will receive test results that are both fast, accurate, and trustworthy."

Every facility that conducts COVID-19 testing is considered a "laboratory" and must be certified under CLIA. To make certification easy, CMS implemented an expedited review process at the beginning of the public health emergency and recently released a <u>quick-start guide</u> that helps laboratories with the application process. It is imperative to public safety that facilities apply for CLIA certification and only operate within the scope of that

certification to prevent false results that could adversely alter diagnosis, treatments, and contribute to the further spread of COVID-19.

Since August 12, 2020, CMS issued 171 cease and desist letters to entities across the U.S. that were testing for COVID-19 without an appropriate CLIA certificate. Of those 171 letters, 34% went to facilities conducting laboratory testing without a CLIA certificate and 66% were issued to laboratories performing COVID-19 testing outside the scope of the existing CLIA certification. The letters ordered these laboratories to stop immediately to safeguard the integrity of COVID-19 testing and protect patients from potential endangerment if they provided inaccurate or unreliable test results. Following receipt of the letter, laboratories are required to provide CMS an attestation certifying they have ceased testing.

In the letters, CMS provided non-certified laboratories with information on how to become CLIA certified and encouraged certified laboratories to obtain the proper CLIA certification to resume testing. CMS has taken this action to promote compliance with CLIA and keep patients safe.

Protect Your Patients: Give Them a Flu Shot

The CDC recommends annual flu shots for everyone 6 months and older. Vaccinate by the end of October – your recommendation makes a difference.

Flu shots are free for your Medicare patients if you accept assignment. Medicare Part B covers one flu shot per flu season and additional flu shots if medically necessary.

For More Information:

- CMS Flu Shot webpage
- CDC Flu website

Events

Medicare Part A Cost Report: New Bulk e-Filing Feature Webcast — October 29

Thursday, October 29 from 1 to 2:30 pm ET

Register for Medicare Learning Network events.

Medicare Part A providers: Learn how to e-file multiple cost reports in the Medicare Cost Report e-Filing (MCReF) system at the same time. While all provider organizations can benefit from this optional feature, organizations that need to file cost reports for multiple facilities may find it most helpful. Topics:

- Overview of new bulk e-filing, including functionality and layout
- Review of accessing the system and transmitting and tracking your cost report
- Frequently asked questions

Use MCReF to:

- Submit cost reports (Individually or in bulk) with fiscal years ending on or after December 31, 2017
- Track the status of cost reports with fiscal years ending after December 31, 2009

You have the option to electronically transmit your cost report through MCReF or mail or hand deliver it to your MAC. You must use MCReF if you choose to submit electronically.

A question and answer session follows the presentation. You may send questions in advance to OFMDPAOQuestions@cms.hhs.gov with "Medicare Cost Report e-Filing System Webcast" in the subject line. We'll answer your questions during the webcast or use them to develop materials. For more information, see the MCRef MLN Matters Article, and MCRef webpage.

If you can't stream audio through your computer for this webcast, you can call in.

Target Audience: Medicare Part A providers and organizations that file cost reports for providers.

MLN Matters® Articles

New Waived Tests

CMS issued a new MLN Matters Article MM11982 on <u>New Waived Tests</u>. Learn about new laboratory waived tests approved by the FDA.

January 2021 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

CMS issued a new MLN Matters Article MM12020 on <u>January 2021 Quarterly Average Sales Price (ASP)</u>
<u>Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files</u>. Learn about new and revised pricing files.

October 2020 Integrated Outpatient Code Editor (I/OCE) Specifications Version 21.3 — Revised

CMS revised MLN Matters Article MM11944 on October 2020 Integrated Outpatient Code Editor (I/OCE) Specifications Version 21.3 to update the summary of modifications for this quarter.

Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index, and Hospice Pricer for FY 2021 — Revised

CMS revised MLN Matters Article MM11876 on <u>Update to Hospice Payment Rates</u>, <u>Hospice Cap</u>, <u>Hospice Wage Index and Hospice Pricer for FY 2021</u> to change the hourly continuous home care rates.

Publications

Provider Compliance Tips for Glucose Monitors and Diabetic Accessories/Supplies — Revised

CMS revised the <u>Provider Compliance Tips for Glucose Monitors</u>, and <u>Diabetic Accessories/Supplies</u> Medicare Learning Network Fact Sheet. Learn:

- Reasons for denials
- How to prevent denials

Multimedia

Coverage of an Annual Wellness Visit Video

Watch the Coverage of an Annual Wellness Visit Video to learn about:

- Differences between the Annual Wellness Visit (AWV), Initial Preventive Physical Examination, and routine physical exam
- Documentation expectations and requirements

For more information about health risk assessments, coding, diagnosis, billing, and initial and subsequent components, see the <u>AWV</u> Booklet.

Information for Medicare Patients

Medicare Health and Drug Plans Receive Star Ratings

On October 8, CMS announced that Medicare beneficiaries will continue to have access to high-quality Medicare Advantage and Part D prescription drug plans in 2021. According to the latest data, quality ratings of Medicare Advantage and Medicare Part D drug plans remain strong. Most Medicare beneficiaries – about 77% – who enroll in Medicare Advantage plans with drug coverage will be in plans with four or more stars in 2021. That compares with 69% of beneficiaries enrolled in such plans in 2017. Almost half – about 49% – of Medicare Advantage plans that offer prescription drug coverage will have an overall rating of four stars or higher, up from about 45% in 2017. The average Star Rating for all Medicare Advantage plans with prescription drug coverage improved to 4.06 out of 5 stars in 2021 from 4.02 in 2017.

Medicare Open Enrollment begins October 15 and ends December 7. During this time, Medicare beneficiaries can compare coverage options like Original Medicare and Medicare Advantage, and choose health and drug plans for 2021. Medicare health and drug plan costs and covered benefits can change from year to year, so people with Medicare should look at their coverage choices and decide on the options that best meet their health needs. They can visit Medicare.gov, call 1-800-MEDICARE, or contact their State Health Insurance Assistance Program. For more information, visit the Part C and D Performance Data webpage.

See the full text of this excerpted CMS Press Release (issued October 8).

Like the newsletter? Have suggestions? Please let us know!

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