

Multiple Program Updates

Background

Now that the major release of information from CMS has passed, nThrive has determined that pooling minor updates into a single publication may be the most efficient mechanism for sharing information with providers. Detailed information on a variety of topics may still be found on the nThrive portal at <https://www.nthrive.com/covid19>.

In this update we address the following information:



COVID-19 Testing Price Transparency

On October 28, 2020 CMS announced the release of an Interim Final Rule with Comment Period (IFC) that primarily addresses access and reimbursement to Coronavirus vaccines and therapeutics. The IFC also addresses publication of a provider's cash price for Coronavirus or COVID-19 testing.

The IFC states: "section 3202(b)(1) of the CARES Act requires each provider of a diagnostic test for COVID-19 to make public the cash price for such test on a public internet website of such provider during the emergency period declared under section 319 of the PHS Act. Section 3202(b)(2) of the CARES Act authorizes the Secretary to impose a civil monetary penalty (CMP) on any provider of a diagnostic test for COVID-19 that does not make public its cash price for such test in compliance with section 3202(b)(1) of the CARES Act and that has not completed a corrective action plan (CAP) to comply with that section. The statute states that the amount of the CMP must not exceed \$300 per day that the violation is ongoing."¹

CMS is adopting in this IFC policies that implement the requirement in section 3202(b) of the CARES Act that providers of diagnostic tests for COVID-19 make public their cash price for such tests on the internet. Specifically, they are finalizing the following:

1. definitions of "provider of a diagnostic test for COVID-19" (herein referred to as "provider"), "diagnostic test for COVID-19" (herein referred to as "COVID-19 diagnostic test"), and "cash price";
2. requirements for making public cash prices; and
3. penalties for non-compliance with the cash price posting requirements.

The IFC further clarifies that such COVID-19 diagnostic tests are currently billed by providers using HCPCS and CPT codes including, but not limited to: CPT codes 86408, 86409, 87635, 87426, 86328, and 86769 and HCPCS codes U0001 through U0004. CMS intends this list of billing codes to be illustrative, however, not exhaustive.

The IFC continues at great length defining these terms, and requirements for posting the cash price. Providers may access this IFC at <https://www.cms.gov/files/document/covid-vax-ifc-4.pdf>.



HCPCS Codes for Cost-Sharing Waiver for COVID-19 Testing

CMS has waived cost-sharing for items and services furnished to an individual during healthcare provider visits that result in an order for or administration of an in vitro diagnostic product described above but only to the extent of the following.

- ✓ Service was rendered during one of the following visits;
 - Office visits (which includes in-person visits and telehealth visits)
 - Urgent care center visits
 - Emergency room visits
 - COVID-19 drive-through screening and testing sites where licensed healthcare providers are administering COVID-19 diagnostic testing
- ✓ Items and services relate to the furnishing or administration of the product; or

- ✓ Evaluation of the individual for purposes of determining the need of the individual for such product. If the individual's attending provider determines that other tests (e.g., influenza tests, blood tests, etc.) should be performed to determine the need of such individual for COVID-19 diagnostic testing, and the visit results in an order for, or administration of, COVID-19 diagnostic testing, the plan or issuer must provide coverage for the related tests.

To help providers identify those related services and to apply Modifier CS, Cost-sharing waived, CMS published a list on August 27, 2020 that includes the following codes:²

G0463	99304-99310	99334-99337
C9803	99315	99339-99345
G0378-G0384	99316	99347-99350
99281-99285	99318	98970-98972
99291	99324-99328	99421-99423



Public Health Emergency Modifier and Condition Code

Due to the large volume and scope of blanket waivers and flexibilities that have been released over the past months, CMS is clarifying which require the usage of Modifier CR, *catastrophe/disaster related*; or Condition code DR, *disaster related*, when submitting claims to Medicare. The extensive chart found at <https://www.cms.gov/files/document/se20011.pdf> identifies those blanket waivers and flexibilities for which CMS requires the use of the modifier or condition code. Submission of the modifier or condition code is not required for any waivers or flexibilities not included in this chart.



Expanded Access and Emergency Use Authorization Condition Codes

On November 20, 2020 CMS released Condition code "90" in order to allow providers to report when the service is provided as part of an Expanded Access approval and Condition code "91" in order to allow providers to report when the service is provided as part of an Emergency Use Authorization.³

Since the 1970s, the U.S. Food and Drug Administration (FDA) has facilitated making investigational drugs available to patients with serious diseases or conditions when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient's disease or condition. The FDA's Expanded Access (EA) process was formalized through regulation in 1987 (drugs and biologics) and 1996 (devices), and EA was further codified in law in 1997. The EA program provides a process for patients

to obtain authorization to use an investigational medical product for treatment use that has not been FDA approved for use outside of a clinical trial setting.

The EUA authority allows the FDA to help strengthen the nation's public health protections against Chemical, Biological, Radiological, and Nuclear (CBRN) threats by making available the use of Medical Countermeasures (MCMs) needed during Public Health Emergencies (PHEs).⁴

Effective for claims received on or after February 1, 2021 providers shall append the newly created Condition code 90 to claims with Expanded Access (EA) services; and Condition code 91 to claims with Emergency Use Authorization (EUA) services.



Repayment Terms for Medicare Loans Made to Providers During COVID-19

In an MLN Special Edition released on October 8, 2020 CMS announced amended terms for payments issued under the Accelerated and Advance Payment (AAP) Program. New recoupment terms allow providers and suppliers one additional year to start loan payments.⁵

Providers were initially required to make payments starting in August of this year, but with this action, repayment will be delayed until one year after payment was issued. After that first year, Medicare will automatically recoup 25% of Medicare payments otherwise owed to the provider or supplier for 11 months. At the end of the 11-month period, recoupment will increase to 50% for another 6 months. If the provider or supplier is unable to repay the total amount of the AAP during this time-period (a total of 29 months), CMS will issue letters requiring repayment of any outstanding balance, subject to an interest rate of 4%.

Providers may also request an Extended Repayment Schedule (ERS) if they are experiencing financial hardships. An ERS is a debt installment payment plan that allows a provider or supplier to pay debts over the course of three years, or, up to five years in the case of extreme hardship.

CMS encourages providers and suppliers to contact their MAC for information on how to request an ERS. To allow even more flexibility in paying back the loans, the \$175 billion issued in Provider Relief funds can be used towards repayment of these Medicare loans.

Additional information may be found at:

<https://www.cms.gov/files/document/accelerated-and-advanced-payments-fact-sheet.pdf>

<https://www.cms.gov/files/document/covid-advance-accelerated-payment-faqs.pdf>



2021 COVID-19 Testing Payment

In April 2020 CMS increased the Medicare payment to laboratories for high throughput COVID-19 diagnostic tests from approximately \$51 to \$100 per test. On October 15, 2020 CMS announced that starting January 1, 2021, Medicare will pay \$100 only to laboratories that complete high throughput COVID-19 diagnostic tests within two calendar days of the specimen being collected. Laboratories that take longer than two days to complete these tests will be paid a rate of \$75.⁶

CMS is establishing these requirements to support faster high throughput COVID-19 diagnostic testing and to ensure all patients (not just Medicare patients) benefit from faster testing and that patients who test positive for the virus are alerted quickly so they can self-isolate and receive medical treatment.

Medicare initially raised the payment for tests performed on high-throughput equipment. With this action they will lower the base payment amount for COVID-19 diagnostic tests run on high-throughput technology to \$75 in accordance with their assessment of the resources needed to perform those tests. Also starting January 1, 2021, Medicare will make an additional \$25 add-on payment to laboratories for a COVID-19 diagnostic test run on high throughput technology if the laboratory:

1. completes the test in two calendar days or less, and
2. completes most of their COVID-19 diagnostic tests that use high throughput technology in two calendar days or less for all of their patients (not just their Medicare patients) in the previous month.

Laboratories that complete a majority of COVID-19 diagnostic tests run on high throughput technology within two days will be paid \$100 per test by Medicare, while laboratories that take longer will receive \$75 per test.

To obtain the full payment CMS has established a new add-on payment of \$25 as identified by HCPCS code U0005. As required by the HCPCS code U0005 descriptor, *Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, CDC or non-CDC, making use of high throughput technologies, completed within two calendar days from date and time of specimen collection. (List separately in addition to either HCPCS code U0003 or U0004)*, this add-on payment may be billed with either HCPCS code U0003 or HCPCS code U0004 when the applicable test is completed within two calendar days of the specimen being collected.

Laboratories that do not complete the test making use of high throughput technologies for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 within two calendar days may not bill HCPCS code U0005 and will not receive the \$25 add-on payment.

CMS updated their FAQ document with several questions related to this topic. One response specified: "In the circumstance that the laboratory has not completed 51% of CDLTs for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 (for all patients) in two calendar days from the date the specimen was collected during the applicable month, then it may not bill for HCPCS code U0005 with either HCPCS code U0003 or U0004."

The full list of Q&A can be found at <https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf>.



Additional Supplies, Materials and Clinical Staff Time

The following new CPT code is effective for dates of service on or after September 8, 2020 and allows free standing physician practices to report additional costs related to the Public Health Emergency:

- ✓ **99072** – *Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency as defined by law, due to respiratory-transmitted infectious disease*

The code has been assigned Procedure Status B which indicates it is bundled into other service payments, thus, providers would not receive additional payment.



Non-Physician Practitioner Billing

A November 12, 2020 MLN bulletin calls attention to the non-physician telephone assessment and management codes. During the COVID-19 Public Health Emergency (PHE), non-physician practitioners who are eligible to bill Medicare directly, including registered dietitians and nutrition professionals, may bill for audio-only telephone assessment and management services:⁷

- ✓ CPT codes 98966-98968
- ✓ Dates of service on or after March 1 until the end of the PHE



Acute Hospital Care at Home

In a November 25, 2020 news release CMS Administrator Seema Verma said: “We’re at a new level of crisis response with COVID-19 and CMS is leveraging the latest innovations and technology to help health care systems that are facing significant challenges to increase their capacity to make sure patients get the care they need. With new areas across the country experiencing significant challenges to the capacity of their health care systems, our job is to make sure that CMS regulations are not standing in the way of patient care for COVID-19 and beyond.”⁸

Subsequently, CMS stated they are outlining unprecedented comprehensive steps to increase the capacity of the American health care system to provide care to patients outside a traditional hospital setting amid a rising number of COVID-19 hospitalizations across the country. These flexibilities include allowances for safe hospital care for eligible patients in their homes and updated staffing flexibility designed to allow ambulatory surgical centers (ASCs) to provide greater inpatient care when needed.

Building on CMS’s previous actions to expand the availability of telehealth across the nation, these actions are aimed at allowing health care services to be provided outside a hospital setting while maintaining capacity to continue critical non-COVID-19 care, allowing hospitals to focus on the increased need for care stemming from public health emergency (PHE).

CMS is expanding on the Hospital Without Walls waiver by executing an innovative Acute Hospital Care At Home program, providing eligible hospitals with unprecedented regulatory flexibilities to treat eligible patients in their homes. This program was developed to support models of at-home hospital care throughout the country that have seen prior success in several leading hospital institutions and networks, and reported in academic journals, including a major study funded by a Healthcare Innovation Award from the Center for Medicare and Medicaid Innovation (CMMI).

The program clearly differentiates the delivery of acute hospital care at home from more traditional home health services. While home health care provides important skilled nursing and other skilled care services, Acute Hospital Care at Home is for beneficiaries who require acute inpatient admission to a hospital and who require at least daily rounding by a physician and a medical team monitoring their care needs on an ongoing basis.

CMS has launched an online portal <https://qualitynet.cms.gov/acute-hospital-care-at-home> to streamline the waiver request process and allow hospitals and healthcare systems to submit the necessary information to ensure they meet the program’s criteria to participate. CMS will also closely monitor the program to safeguard beneficiaries by requiring hospitals to report quality and safety data to CMS on a frequency that is based on their prior experience with the Hospital At Home model.

In the Hospital At Home FAQ CMS indicates they plan to host a series of webinars with both academic and private industry leaders the week of November 30th, 2020. These are intended to disseminate best practices and answer questions, as well as to help organizations decide whether they are ready to treat patients with this level of care. CMS will also host an orientation phone call for all participating programs during the week of November 30, 2020.

Additional information may be found at these links:

<https://www.cms.gov/files/document/what-are-they-saying-hospital-capacity.pdf>

<https://www.cms.gov/files/document/covid-hospital-without-walls-faqs-ascs.pdf>

<https://www.cms.gov/files/document/covid-acute-hospital-care-home-faqs.pdf>

Guidance

- ✓ Review each update and evaluate current practice.
- ✓ Enroll in programming as appropriate.
- ✓ Add additional charges and codes to the CDM.
- ✓ Educate staff to ensure accurate capture and reporting of services.



Sources

1. <https://www.cms.gov/files/document/covid-vax-ifc-4.pdf>
2. <https://www.cms.gov/files/document/cs-waiver-ops-codes.pdf>
3. Medicare Transmittal 10470, November 20, 2020.
4. Medicare MLN MM12049, November 20, 2020.
5. Medicare MLN Special Edition, October 8, 2020.
6. <https://www.cms.gov/files/document/cms-ruling-2020-1-r2.pdf>
7. https://www.cms.gov/outreach-and-education/outreachffsprovpartprogprovider-partnership-email-archive/2020-11-12-mlnc#_Toc55891815
8. <https://www.cms.gov/newsroom> ■