Advancing Transfusion and Cellular Therapies Worldwide

Department of Health and Human Services Announces Payment Policy for COVID-19 Convalescent Plasma

On October 28, the Department of Health and Human Services (HHS) released an interim final rule in which the Centers for Medicare & Medicaid Services (CMS) sets forth the Medicare payment policies for COVID-19 convalescent plasma (CCP) furnished in the hospital inpatient and outpatient settings of care. Additionally, the interim final rule implements a price transparency requirement for COVID-19 diagnostic tests.

HHS released the interim final rule entitled, "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency," before it was placed on public display or published in the *Federal Register*. It will be immediately effective on the date of display for public inspection.

Medicare Hospital Inpatient Payment Policy: CMS establishes a new add-on payment, the new COVID-19 Treatments Add-on Payment (NCTAP), that will be available for certain novel COVID-19 treatments provided to hospital inpatients for the remainder of the public health emergency (PHE). CMS specifies that only two treatments currently qualify for the NCTAP, including CCP and remdesivir. However, as new therapies receive an EUA or approval to treat COVID-19, they will qualify for the NCTAP.

The purpose of the NCTAP is to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments by partially offsetting costs that exceed the Medicare payment. The NCTAP will be provided on top of the temporary adjustment that hospitals receive for treating individuals diagnosed with COVID-19 during the COVID-19 PHE.

To be eligible for a NCTAP, the following criteria must be satisfied:

- The use of a drug or biological product authorized to treat COVID-19 [is] indicated in section "I. Criteria for Issuance of Authorization" of the current letter of authorization for the drug or biological product, or the drug or biological product must be approved by the FDA for treating COVID-19.
- The case must also be eligible for the 20 percent increase in the weighting factor for the assigned MS-DRG for an individual diagnosed with COVID-19 discharged during the period of the PHE for COVID-19.
- The operating cost of the case must exceed the operating Federal payment under the IPPS, including the 20 percent add-on payment described above.

CMS set the NCTAP amount equal to the lesser of: (1) 65 percent of the operating outlier threshold for the claim or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment, including the payment adjustment established by the CARES Act. CMS will use procedure codes XW13325 (Transfusion of Convalescent Plasma (Nonautologous) into Peripheral Vein, Percutaneous Approach, New Technology Group 5) and XW14325 (Transfusion of Convalescent Plasma (Nonautologous) into Central Vein, Percutaneous Approach, New Technology Group 5) to identify cases using convalescent plasma.

Importantly, CMS specifies that hospitals should not seek additional payment on the claim for a drug or biological procured or provided by a government entity to a provider at no cost to the provider to

diagnose or treat patients with known or suspected COVID-19. Therefore, if CCP has been paid for by BARDA and is provided to a hospital at no cost, the hospital should not seek payment using the NCTAP.

Medicare Hospital Outpatient Payment Policy: CMS indicates that separate payments will be made available under the Medicare hospital outpatient prospective payment system (OPPS) for new drugs and biologicals, including blood products, that receive an EUA for treating COVID-19 in the outpatient setting or are approved by FDA for treating COVID-19 in the outpatient setting, or where a drug or biological product approved under an existing EUA is authorized for use outside of the hospital inpatient setting. CMS anticipates adding new codes describing the treatments as soon as practicable once they are available.

Any new COVID-19 treatment that meets the following two criteria will, for the remainder of the PHE for COVID-19, be separately paid and will not be packaged into a C-APC when it is provided on the same claim as the primary C-APC service:

- The treatment must be a drug or biological product (which could include a blood product) authorized to treat COVID-19, as indicated in section "I. Criteria for Issuance of Authorization" of the letter of authorization for the drug or biological product, or the drug or biological product must be approved by the FDA for treating COVID-19.
- The EUA for the drug or biological product (which could include a blood product) must authorize the use of the product in the outpatient setting or not limit its use to the inpatient setting, or the product must be approved by the FDA to treat COVID-19 disease and not limit its use to the inpatient setting.

The separate payment will result in an additional copayment of 20 percent of the cost of the new COVID-19 treatment, up to the amount of the inpatient deductible.

Price Transparency for COVID-19 Diagnostic Tests: The interim final rule implements a requirement from the CARES Act that providers of diagnostic tests for COVID-19 make public their cash price for such tests on the internet. CMS is enforcing this requirement by establishing civil-monetary penalties equal to $300 per day for non-compliance.

CMS defines the COVID-19 diagnostic tests subject to the price transparency requirement by referencing a section in the CARES Act that refers to "an in vitro diagnostic test defined in section 809.3 of title 21, Code of Federal Regulations… for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19,…." In the preamble to the regulation, CMS specifies that "COVID-19 diagnostic tests" "include all in vitro diagnostic tests, which include molecular, antigen, and serological tests" and explains that serology testing "is used to look for the presence of antibodies produced by the body in response to infections." CMS notes that these 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. The agency indicates that a "provider of a diagnostic test for COVID-19" is "any facility that performs one or more COVID-19 diagnostic tests."

AABB is working to clarify the scope of the price transparency requirements, and their potential impact on AABB members.