hfma
healthcare financial management association

HFMA Summary
Interim Final Rule: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, **October 28, 2020**

On Wednesday, October 28, CMS, the Department of Health and Human Services, Internal Revenue Service, Department of the Treasury, Employee Benefits Security Administration and Department of Labor issued an interim final rule (IFC) to ensure the coverage of COVID-19 vaccines. Additionally, the IFC addresses a number of ancillary issues – including price transparency for COVID-19 tests, Medicare payment for new COVID-19 treatments, Medicaid enrollment flexibility during the pandemic, and extension of performance year (PY) 5 in the Comprehensive Care for Joint Replacements (CJR) program. The following is a summary of key provisions included in the IFC.

1) **Medicare Inpatient Prospective Payment System (IPPS) New COVID– 19 Treatments Add-on Payment (NCTAP) for the remainder of the Public Health Emergency (PHE):** Effective for discharges occurring on or after the effective date of this IFC and until the end of the PHE, CMS is creating a New COVID–19 Treatments Add-on Payment (NCTAP) under the IPPS for COVID-19 cases that meet certain criteria (described below).

   First, the case must include the use of a drug or biological product that is covered by an emergency use authorization to treat COVID-19 or the drug or biological product must be approved by the Food and Drug Administration (FDA) for treating COVID-19. There are currently (as of October 28) only two products – COVID-19 convalescent plasms and Veklury® (remdesivir) that meet this requirement.

   Second, the case must also be eligible for the 20% 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 under section 3710 of the CARES Act. CMS may conduct post-payment medical review to confirm the presence of a positive COVID-19 laboratory test and, if no such test is contained in the medical record, the NCTAP will be recouped.

   Third, the operating cost of the case must exceed the operating Federal payment under the IPPS, including the add-on payment under section 3710 of the CARES Act. The cost of the case is determined by multiplying the covered charges by the operating cost-to-charge ratio, the same way it is determined for new technology add-on payments and operating outlier payments.

   CMS is setting the NCTAP amount for a case that meets the NCTAP eligibility criteria equal to the lesser of: (1) 65% of the operating outlier threshold for the claim or (2) 65% of the amount by which the costs of the case exceed the standard DRG payment, including the adjustment to the relative weight under section 3710 of the CARES Act.

   CMS notes that a hospital should not seek additional payment on the claim for drugs or biologicals procured or provided by a governmental entity to a provider at no cost to the provider to diagnose or treat patients with known or suspected COVID-19.

   CMS will use ICD-10-PCS procedure codes XW033E5 (“Introduction of Remdesivir Anti-infective into Peripheral Vein, Percutaneous Approach, New Technology Group 5”) and XW043E5 (“Introduction of Remdesivir Anti-infective into Central Vein, Percutaneous Approach, New

Technology Group 5") to identify cases using remdesivir and ICD-10-PCS 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.

2) **Medicare Outpatient Prospective Payment System (OPPS) Separate Payment for New COVID–19 Treatments Policy for the remainder of the PHE**: Effective for services furnished on or after the effective date of this rule and until the end of the PHE for COVID-19, CMS is creating an exception to its OPPS comprehensive ambulatory payment classification (C-APC) policy to ensure separate payment for new COVID–19 treatments that meet certain criteria. Under this exception, any new COVID-19 treatment that meets the two criteria below will, for the remainder of the PHE for COVID-19, always 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. Note that this separate payment will result in an additional copayment of 20% of the cost of the new COVID-19 treatment, up to the amount of the inpatient deductible.

   First, 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.

   Second, the emergency use authorization (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.

   As of the date of issuance of this IFC, there are two drug or biological products that meet the first criterion (Veklury (remdesivir) and COVID-19 convalescent plasma), but neither of these products is authorized or approved for use in the outpatient setting and, as a result, no product meets the second criterion.

   All generally applicable statutory and regulatory requirements for Medicare payment under the OPPS must continue to be met, and that OPPS payment will only be available to the extent that the new COVID-19 treatment meets all coverage requirements under Medicare, including that the use of a drug or biological product is medically reasonable and necessary for the patient. No applicable Medicare requirements during the PHE are being waived by the creation of this C-APC exception.

3) **Updates to the CJR Model, PY5 During the COVID-19 PHE**: The IFC implements multiple changes to the model which are detailed below.

a) *Six Month Extension of Performance Year 5*: CMS is implementing a 6-month extension to CJR PY 5. The model will now end on September 30, 2021. CMS is extending PY5 an additional 6 months to provide for continuity of model operations with the same scope while it continues to consider comments received on its proposal to extend the model to PY6 through 8 and adopt other changes to the model.

b) *Multiple Reconciliations for PY5*: CMS will conduct two initial, and two final, reconciliations of PY5. The first initial reconciliation will apply to the first 12 months of PY5 in order to maintain consistency with the 12 month reconciliation cycles for previous PYs 2-4, and the second initial reconciliation will apply to the remaining 9 months of PY5. To minimize confusion, CMS refers to these two subsets of PY5 as PY subset 5.1 and 5.2, respectively.

The initial reconciliation of PY subset 5.1 will occur 14 months after the start of PY5, which is the same timeline as would have occurred PY5 under the December 2017 final rule. After the usual 2-month period of claims runout, the initial reconciliation for PY subset 5.1 episodes will begin in late February of 2021 using 12 months of claims from CY20 to calculate reconciliation payments, with the resulting amounts netted against the results of the concurrent PY4 final reconciliation calculation when CMS issues reports and reconciliation amounts to participants in June 2021. Participants can expect to receive their 2021 reconciliation reports on approximately the same schedule as in previous model years.

The nine additional months of PY5 (PY subset 5.2) will be reconciled one full calendar year after the reconciliation of PY4 final/performance year subset 5.1 initial. CMS will use claims data for the initial reconciliation of PY subset 5.2 that reflect a 2-month period of claims runout, as CMS has for PY1-4 and PY subset 5.1. In short, PY subset 5.2 will run from January 1, 2021 through September 30, 2021.

Consistent with using two months of claims run out, CMS will pull claims for the initial reconciliation in December 2021. However, CMS will not reconcile PY subset 5.2 until late February 2022 along with the final reconciliation for PY subset 5.1. This means that CMS will not begin reconciliation calculation for PY subset 5.2 until five months after the end of PY subset 5.2 in order to align the initial reconciliation calculation for PY subset 5.2 with the timing of the subsequent reconciliation calculation for PY subset 5.1.

The final reconciliation calculation for PY subset 5.2 will occur one year after the initial reconciliation of PY subset 5.2. Although CMS will use claims data that were available 14 months after the end of PY subset 5.2 for the subsequent reconciliation (as set forth in 42 CFR 510.305(i)(1)), as with the initial reconciliation, CMS will not begin the subsequent reconciliation calculation process until 17 months after the end of PY subset 5.2. CMS would begin the final reconciliation calculation for PY subset 5.2 in late February 2023 with reconciliation payment amounts and reports issued in June, because input files that are required for the final reconciliation will not be available until 17 months after the end of PY subset 5.2.

The following table provides the reconciliation timelines for PY4 and 5.

Performance Year (PY)	Performance Period	Initial Reconciliation Calculation Start	Subsequent Reconciliation Calculation Start	Reconciliation Amount (+/-)
4	01/01/2019 to 12/31/2019	2 months after 12/31/2019: Late February 2020	14 months after 12/31/2019: Late February 2021	Net PY3 and PY4 reconciliation amounts
5 (two periods)	01/01/2020 to 09/30/2021			
Subset 5.1	01/01/2020 to 12/31/2021	2 months after 12/31/2020: Late February 2021	14 months after 12/31/2020: Late February 2022	Net PY4 and PY5.1 reconciliation amounts
Subset 5.2	01/01/2021 to 09/30/2021	5 months after 09/30/2021: Late February 2022	17 months after 09/30/2021: Late February 2023	Net PY5.1 and PY5.2 reconciliation

As part of the separate reconciliation calculation processes for PY subsets 5.1 and 5.2, CMS will calculate a separate Composite Quality Score (CQS) for each of PY subsets 5.1 and 5.2, including a separate set of quality improvement points and quality performance points for each PY subset.

c) *Technical Changes to Accommodate MS-DRGs 521 and 522*: As of October 1, 2020, the CJR model includes episodes when the MS-DRG assigned at discharge for an anchor hospitalization is one of two new MS-DRGs adopted in the FY21 IPPS final rule (85 FR 58432): MS-DRG 521 ("Hip Replacement with Principal Diagnosis of Hip Fracture with Major Complications and Comorbidities (MCC)" and MS-DRG 522 ("Hip Replacement with Principal Diagnosis of Hip Fracture, without MCC"). This change ensures that hip replacements with a principal diagnosis of hip fracture, with and without MCC, will continue to trigger CJR model episodes even though they are now assigned to these new DRGs rather than MS-DRGs 469 and 470.

As of October 1, 2020, the quality adjusted target prices for MS-DRGs 469 and 470 with hip fracture will apply to episodes initiated by the new MS-DRGs 521 and 522, respectively, for the remainder of PY5 (including both PY subsets 5.1 and 5.2).

d) *Extreme and Uncontrollable Circumstances Policy*: The extreme and uncontrollable circumstances (E&UC) adjustment for COVID-19 will expire on March 31, 2021 or the last day of the emergency period, whichever is earlier. CMS is adopting a more targeted adjustment, which will apply after March 31, 2021 or the last day of emergency period (whichever is earlier), so that financial safeguards continue to apply for CJR episodes during which a CJR beneficiary receives a positive COVID-19 diagnosis.

Currently under the E&UC policy, actual episode payments are capped at the target price determined for that episode, apply to fracture or non-fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins or that occurs through the termination of the emergency period.

In order to account for CJR beneficiaries with a positive COVID-19 diagnosis during a CJR episode that initiates after the adjustments for E&UC specified CMS is capping actual episode payments at the quality-adjusted target price for the episode, effectively waiving downside risk for all episodes with actual episode payments that include a claim with a COVID-19 diagnosis code. This policy will apply after March 31, 2021 or the last day of the PHE, whichever occurs earlier.

4) **Medicare Part B Coverage of COVID-19 Vaccine:** Section 3713 of the CARES Act provides for coverage of the COVID-19 vaccine under Part B of the Medicare program without any beneficiary cost sharing. The rule states that CMS will provide coverage, without cost sharing, under Medicare Part B for any vaccine that has received an EUA.

   The Medicare allowed amount for the COVID-19 vaccine will also be 95% of the average wholesale price (or reasonable cost, for example under OPPS). Because there are many product-specific factors that are still unknown, including the possibility of differential costs associated with each COVID-19 vaccine product and storage and administration requirements, CMS anticipates establishing a unique administration code for each COVID-19 vaccine product. To that end, CMS anticipates that payment rates for the administration of other Part B preventive vaccines and related services, such as the flu and pneumococcal vaccines, would serve to inform the payment rates for administration of COVID-19 vaccines.

   Due to the urgent circumstances of the PHE, CMS will not initially use the notice and comment process to set coding policies and payment rates for COVID-19 vaccine administration. Instead, as soon as practicable after the authorization or licensure of each COVID-19 vaccine product by the FDA, CMS will announce the interim coding and a payment rate for its administration (or, in the case of the OPPS, an APC assignment for each vaccine product's administration code), taking into consideration any product-specific costs or considerations involved in furnishing the service. However, it will address these issues after the vaccine is available in its annual rule making cycle for the Medicare Physician Fee Schedule, OPPS, and other applicable rules.

   CMS believes it would be appropriate to allow COVID-19 vaccinations to be provided through the mass immunization and roster billing process that is in place for flu and pneumococcal vaccinations.

5) **Medicare Advantage COVID-19 Vaccine:** Statutes and regulations related to Medicare Advantage (MA) plans provide that when a National Coverage Determination (NCD) or legislative change in benefits, such as the addition of Part B coverage of a COVID-19 vaccine and

its administration, results in significant costs that have not been included in the capitation payments made to MA plans, coverage of the new benefit will be provided through the Medicare fee-for-service (FFS) program until the capitation payments take the new significant costs into account.

The payment rates for MA organizations for contract years 2020 and 2021 have been set without including the costs for a COVID-19 vaccine and its administration. Therefore, if coverage of a COVID-19 vaccine and its administration during that period results in significant costs, Medicare FFS is required to cover the vaccine and its administration.

If the estimated cost of an NCD or legislative change represents at least 0.1% of the national average per capita costs or the average cost of furnishing a single service exceeds the cost threshold established in using the statutory formula, it is considered a significant cost and the Medicare FFS program provides coverage for the service until the costs are factored into MA payments.

The significant cost threshold will be met assuming that the projected cost per beneficiary-per-year is greater than approximately $13, which is 0.1% of the national average per capita costs. If the threshold is reached, Medicare beneficiaries enrolled in MA plans will receive coverage of the COVID-19 vaccine and its administration through the Medicare FFS program and would be able to access the COVID-19 vaccine, without cost sharing, at any FFS provider or supplier that participates in Medicare and is eligible to bill under Part B for vaccine administration, including those enrolled in Medicare as a mass immunizer or a physician, nonphysician practitioner, hospital, clinic or group practice.

CMS is requiring MA plans to cover COVID-19 vaccines provided to MA beneficiaries by an in-network provider without cost sharing for the duration of the PHE. Because the Medicare FFS program covers Part A and Part B items and services furnished to cost plan enrollees by out-of-network healthcare providers that participate in the Medicare FFS program, cost plan enrollees will receive the COVID-19 vaccine and its administration without cost sharing when they go to a healthcare provider that is out of the cost plan's network.

6) **COVID-19 Vaccine Coverage for Medicaid, Children's Health Insurance Program and Basic Health Program (BHP) Beneficiaries:** The Families First Coronavirus Response Act (FFCRA) requires that states' and territories' Medicaid programs may receive a temporary 6.2 percentage point increase in the Federal Medical Assistance Percentage (FMAP). To receive that increase, a state or territory must cover COVID-19 testing services and treatments, including vaccines and the administration of such vaccines, for Medicaid enrollees without cost sharing. CMS is not aware of any states or territories not currently claiming this temporary FMAP increase, or of any state or territory that intends to cease claiming it. Accordingly, Medicaid coverage of a COVID-19 vaccine and its administration, without cost-sharing, is expected to be available for most Medicaid beneficiaries through the end of the quarter in which the PHE for COVID-19 ends.

CMS does not interpret FFCRA section 6008(b)(4) to require states to provide COVID-19 testing and treatment services without cost-sharing, including vaccines and their administration, to eligibility groups whose coverage is limited by statute or under an existing section 1115 demonstration to a narrow range of benefits that would not ordinarily include this coverage, such as groups that receive Medicaid coverage only for COVID-19 testing, family planning services and supplies, or tuberculosis-related services.

The COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing and Treatment of the Uninsured Program (COVID-19 Claims Reimbursement program) administered by the Health Resources and Services Administration (HRSA) is available for reimbursement of a COVID-19 vaccine and vaccine administration costs for individuals who would not receive Medicaid coverage for a COVID-19 vaccine or its administration because their Medicaid coverage is for limited benefit packages only.

While FFCRA section 6008(b)(4) requirement does not apply to the BHP, consistent with the changes made through this rulemaking, during the COVID-19 PHE, BHP plans and Medicaid alternative benefit plans must provide coverage for and must not impose any cost-sharing for "qualifying coronavirus preventive services," including a COVID vaccine, regardless of whether the vaccine is delivered by an in-network or out-of-network provider.

7) **Commercial Coverage of COVID-19 Vaccine**: The department of Health and Human Services (HHS), the Department of Labor, and Department of Treasury require all commercial plans[1] to cover COVID-19 immunizations and their administration as preventative services (without cost sharing) within 15 business days after the immunization has been recommended by the Advisory Committee on Immunization Practices (ACIP) and adopted by the Centers for Disease Control and Prevention (CDC), regardless of whether it appears on the Immunization Schedules of the CDC for routine use.

   Plans and issuers subject to section 2713 of the PHS Act must cover without cost sharing such an immunization and its administration, regardless of how the administration is billed, and regardless of whether a COVID-19 vaccine or any other immunization requires the administration of multiple doses in order to be considered a complete vaccination. This includes coverage without cost sharing of the administration of a required preventive immunization in instances where a third party, such as the federal government, pays for the preventive immunization.

   Further, plans and issuers subject to section 2713 of the Public Health Service Act must cover without cost sharing a qualifying coronavirus preventive service, regardless of whether such service is delivered by an in-network or out-of-network provider. The IFC provides that with respect to a qualifying coronavirus preventive service and a provider with whom the plan or

[1] Includes individual, small group, large group and self-insured plans in which employers contract administrative services to a third party payer – with the exception of those plans that maintain "grandfathered" status.

issuer does not have a negotiated rate for such service (such as an out-of-network provider), the plan or issuer must reimburse the provider for such service in an amount that is reasonable, as determined in comparison to prevailing market rates for such service. The Departments will consider the amount of payment to be reasonable, for example, if the plan or issuer pays the provider the amount that would be paid under Medicare for the item or service.

8) **Price Transparency for COVID-19 Tests:** During the PHE, providers of diagnostic tests for COVID-19 make public the cash price for such tests available on the internet. The provider must make the price for the COVID-19 test and related information available in a conspicuous location on a searchable homepage of the provider's website. The information must be displayed in a manner that is easily accessible, without barriers, and ensures that the information is accessible free of charge, without having to establish a user account or password and without having to submit personal identifiable information.

   All of the following information is required to be made publicly available:

   a. A plain-language description of each COVID-19 diagnostic test that is offered by the provider
   b. The billing code used for each COVID-19 diagnostic test
   c. The provider's cash price for each such COVID-19 diagnostic test
   d. Any additional information as may be necessary for the public to have certainty of the cash price that applies to each COVID-19 diagnostic test

   Providers who do not have their own website must make the same information available in writing within two days of a request and on a sign posted prominently at the location where the provider offers a COVID-19 diagnostic test, if such location is accessible to the public.

   If CMS concludes that the provider is noncompliant with one or more of the COVID-19 test price transparency requirements it may take any of the following actions:

   a. Provide a written warning notice to the provider of the specific violation(s).
   b. Request that the provider submit and comply with a corrective action plan.
   c. Impose a civil monetary penalty on the provider if the provider fails to respond to CMS's request to submit a corrective action plan or to comply with the requirements of a corrective action plan approved by CMS. The maximum daily dollar amount for a civil monetary penalty to which a provider may be subject is $300. Even if the provider is in violation of multiple discrete requirements of this part, the maximum total sum that a single provider may be assessed per day is $300.

9) **Maintenance of Medicaid Enrollment to Received Enhanced FMAP**: States are required, as a condition for receiving the temporary FMAP increase, to maintain beneficiary enrollment in an eligibility group that provides one of three tiers of coverage through the end of the month in

which the PHE for COVID-19 ends, except under the circumstances in which the beneficiary obtained eligibility in error or by fraudulent means.

This provision generally does not require states to provide the exact same (or greater) amount, duration and scope of medical assistance, or maintain the cost-sharing or post-eligibility treatment of income (PETI) liability for a particular beneficiary at the same (or lower) level that was applicable to the beneficiary as of March 18, 2020 or subsequent date of initial enrollment during the PHE. This change is effective immediately upon display of this rule. CMS's previous interpretation continues to apply from the beginning of the quarter up to the date that this IFC is displayed.

However, CMS is requiring states to ensure that beneficiaries who were validly enrolled for benefits as of or after March 18, 2020, with access to minimum essential coverage (MEC) retain access to MEC, and to ensure that beneficiaries with access to testing services and treatment for COVID-19 maintain access to those services.

The first tier of coverage consists of Medicaid coverage that meets the definition of MEC. For beneficiaries whose Medicaid coverage as of or after March 18, 2020 meets the definition of MEC, the state must generally continue to provide Medicaid coverage that meets the definition of MEC throughout the period in which this rule applies. This means that if a state determines a beneficiary ineligible for the group in which he or she is currently enrolled, which provides MEC, and finds the beneficiary eligible for another group that also provides MEC, the state would transition the beneficiary to the new eligibility group. In contrast, if the beneficiary lost eligibility for a group that provides MEC, but gained eligibility for coverage that does not meet the definition of MEC, the state may not move the beneficiary to the new group or demonstration but must instead maintain the beneficiary's access to coverage meeting the definition of MEC during the period in which the rule applies.

The second tier of coverage consists of coverage that is not defined as MEC but that is robust enough to include access to coverage of both testing services and treatment for COVID-19. Some beneficiaries' coverage is limited by statute or existing section 1115 demonstration authority to a very narrow range of services that would not include COVID-19 testing or treatment services, and CMS has not interpreted section 6008(b)(4) of the FFCRA to require states to cover COVID-19 testing and treatment services for those beneficiaries.

However, other Medicaid beneficiaries receive a relatively robust set of benefits, such as pregnancy-related services, which would include testing services and treatment for COVID-19, including vaccines, specialized equipment, and therapies, during the period when FFCRA section 6008(b)(4) applies in a state, but which does not qualify as MEC in all states. States must continue to provide Medicaid coverage that includes coverage of COVID-19 testing services and treatments, including vaccines, specialized equipment, and therapies, to beneficiaries who had access to coverage in tier 2 as of or after March 18, 2020. Thus, states must transition beneficiaries who lose eligibility for tier 2 coverage but gain access to MEC coverage in tier 1 or

to other coverage in tier 2 to the new eligibility group or demonstration, but they may not transition such beneficiaries to coverage that does not include access to testing services and treatment for COVID-19.

The third tier includes coverage that is not MEC and that also does not cover testing services and treatment for COVID-19, including vaccines, specialized equipment, and therapies, under CMS's interpretation of FFCRA section 6008(b)(4). Coverage under tier 3 may include coverage for the eligibility group limited to family planning or the eligibility group for individuals with tuberculosis. If a beneficiary loses eligibility for coverage meeting the tier 3 description during the period in which the FFCRA section 6008(b)(3) requirement applies, and the beneficiary gains eligibility for a group that provides coverage in tier 1 or tier 2, then the state must transfer the beneficiary into that new eligibility group as coverage in those tiers is more robust than coverage in tier 3.

If a beneficiary becomes ineligible for the tier 3 eligibility group or demonstration in which he or she is enrolled and becomes eligible for another eligibility group or demonstration with coverage that is also within tier 3, the state must continue to provide the coverage available through the eligibility group or demonstration for which the beneficiary was eligible as of or after March 18, 2020, unless the beneficiary requests a voluntary termination to transition to the new eligibility group or demonstration. Transitioning a beneficiary from one eligibility group offering tier 3 coverage to another eligibility group offering tier 3 coverage would not satisfy the requirement in 433.400(c)(2)(iii).