hfma
healthcare financial management association

December 2, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9912-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

File Codes: CMS-9912-IFC

Re: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Dear Administrator Verma:

On behalf of the Healthcare Financial Management Association's (HFMA's) 56,000 members, I would like to thank you for CMS's leadership during the COVID-19 Public Health Emergency (PHE). We greatly appreciate the work CMS's staff has undertaken to use its waiver authority to expand access to care via telehealth, allow for hospitals to expand capacity, reduce unnecessary administrative burden, and support providers who are participating in alternative payment models (APMs) in prior interim final rules. The speed and responsiveness with which the agency has moved to address provider concerns is both unprecedented and impressive.

HFMA members strongly support the administration's efforts in the recently released Interim Final Rule, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (hereafter IFC), to ensure that once a COVID-19 vaccine is available, all Americans will have access to it without cost sharing. The IFC includes a number of other provisions that HFMA generally supports. However, our members have specific concerns regarding:

- Medicare Inpatient Prospective Payment System (IPPS): New COVID-19 Treatments Add-on Payment (NCTAP)
- Medicare Outpatient Prospective Payment System (OPPS): Separate Payment for New COVID–19 Treatments
- Updates to the Comprehensive Care for Joint Replacement (CJR) Model, Performance Year (PY) 5 During the PHE

Below please find HFMA members' specific comments on each of these provisions.

Medicare IPPS: New COVID-19 Treatments Add-on Payment
CMS is concerned that financial disincentives will limit Medicare beneficiaries' access to new COVID-19 treatments. Therefore, in an effort to mitigate these incentives, CMS is creating a New COVID–19

Treatments Add-on Payment (NCTAP) under the IPPS for COVID-19 cases that meet certain criteria. In order to qualify for the NCTAP, a case:

1. 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.
2. Must be eligible for the 20% increase in the weighting factor for the assigned MS-DRG for an individual diagnosed with COVID-19.
3. Have operating cost that exceeds the operating Federal payment under the IPPS (including the 20% COVID-19 add-on payment). The cost of the case is determined by multiplying the covered charges by the operating cost-to-charge ratio.

The NCTAP amount for a case that meets the NCTAP eligibility criteria is 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.

HFMA members appreciate CMS's recognition of the significant cost associated with new COVID-19 therapies provided to Medicare beneficiaries who are hospitalized. However, we are deeply concerned that the NCTAP payment methodology will not cover the cost of qualifying new COVID-19 treatments provided to Medicare beneficiaries. And in all likelihood, hospitals will lose money on these cases, increasing the stress on hospitals at a time when they are under considerable financial pressure due to their efforts to protect their communities from the coronavirus. **Therefore, HFMA members strongly recommend that CMS modify the NCTAP payment. The payment should be a cost based "pass-through" tied to the qualifying treatment's ICD-10 code.**

Medicare OPPS: Separate Payment for New COVID–19 Treatments
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 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.

HFMA members appreciate CMS's recognition of the significant cost associated with new COVID-19 therapies provided to Medicare beneficiaries in hospital outpatient departments (HOPDs). **Our members strongly support the exception that ensures separate payment for qualifying COVID-19 treatments provided to Medicare beneficiaries in HOPDs if they would otherwise be packaged with a C-APC.**

The IFC only states that these drugs or biologicals would be "separately payable." **HFMA members request that CMS confirm that qualifying therapies that are excluded from the C-APC would be paid at ASP (average sales price) +6, WAC (wholesale acquisition cost) +3, or 95% of average wholesale price, similar to other separately payable drugs. Similar to our comments on the 2021 OPPS proposed rule,[1] HFMA members are strongly opposed to applying CMS's arbitrarily calculated and inappropriate reduction to the ASP amount for drugs acquired under the 340B program. If CMS finalizes this policy in the CY21 OPPS we strongly recommend that qualifying products be exempt from the payment reduction when they are acquired under the 340B program.**

[1] HFMA Comment Letter to CMS, Oct. 2, 2020.

Updates to the CJR Model, Performance Year (PY) 5 During the PHE
CMS makes multiple changes to the CJR model for PY5 in the IFC. HFMA members would like to take the opportunity to comment on three of the changes.

- *Six-Month Extension of PY5*: CMS is implementing a 6-month extension to CJR PY5. The model will now end on September 30, 2021. CMS is extending PY5 an additional 6 months to provide for continuity of model operations within the same scope while it continues to consider comments received on its proposal to extend the model to PYs 6 through 8 and adopt other changes to the model. I**f CMS intends to finalize its February 20, 2020 proposed rule that would extend the program for three more years, HFMA members generally support a 6-month extension.** We agree that temporarily halting the model while CMS finalizes the February 20, 2020 proposed rule[2] would be highly disruptive for the model's mandatory participants. Beyond the cost incurred from having to restart the program, we are concerned that a hiatus could potentially create confusion with hospitals' physician partners and decrease their engagement in care process improvement efforts.

  As part of this change, CMS requests comment on the duration of PY6. **HFMA members believe that PYs 6-8 should each remain 12-month performance years.** Therefore, PY6 should begin with episodes ending on or after October 1, 2021. Given this change, the model would run through September 30, 2024. As discussed below, our members generally believe that longer intervals between actual performance and feedback to hospital participants and their physician partners has a detrimental impact on the ability to improve care delivery.

- *Multiple Reconciliations for PY5*: **HFMA strongly supports CMS's plan to 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.

  HFMA members share CMS's concerns about increasing the lag time between actual performance and receipt of data/feedback on the results. The timeliness of feedback to providers about their performance is a perennial concern in any alternative payment model. Our members agree that having 23 months transpire between the start of the performance year and receiving initial results would negatively impact physician and provider engagement.

- *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. After the expiration, instead of capping actual episode payments at the target price determined for that episode for all cases (the current policy under the E&UC), the cap will only apply to CJR cases where the Medicare beneficiary has a COVID-19 diagnosis code on the claim.

  CMS adopted the E&UC policy based on its projections of abrupt, large and sustained declines in joint replacement operative volumes, procedures that are largely elective, except when associated with hip fractures. Subsequent analysis by CMS indicates that after the expected early and significant decline, joint replacement procedure performance has rebounded substantially above levels and more quickly than anticipated.

[2] HFMA Comment Letter to CMS, April 23, 2020.

Based on HFMA's analysis of CMS's data we disagree with the conclusion. As shown in Table 1 below, while lower extremity joint replacement (LEJR) volumes have rebounded from their April low (when hospitals canceled non-emergent procedures based on CMS guidance), they have not stabilized (as evidenced by significant swings in volumes in June, July and August) and they are not approaching pre-COVID-19 levels. On a relative basis, volumes in August are lower than they were in March. We note CMS's guidance on non-emergent procedures was released on March 18, which precipitated many providers postponing non-emergent procedures. That guidance had been revised and relaxed by August, so it is telling that volumes for the month of August are still lower on a relative basis than March.

Table 1: CJR Episode Volume Comparison

	February	March	April	May	June	July	August
2019	6,214	6,174	6,515	6,019	5,836	6,060	5,838
2020	5,245	3,374	876	2,242	4,036	3,838	3,090
Change in Volume from Prior Year	-15.6%	-45.4%	-86.6%	-62.8%	-30.8%	-36.7%	-47.1%

HFMA members are deeply concerned that hospitals are still experiencing significant adverse selection in their CJR case mix. We are hearing anecdotally from our members that many relatively healthy (and therefore lower cost) Medicare beneficiaries are continuing to delay non-emergent LEJR procedures. Given the decline in LEJR procedures performed in July and August of 2020, relative to 2019, we believe Medicare's data supports this.

Additionally, given localized concerns about hospital acute and ICU bed capacity some health systems are again deferring non-emergent procedures[3,4,5] to ensure they have sufficient resources to meet the needs of patients afflicted with COVID-19. Given the current trajectory of COVID-19 cases, we are concerned this will be more common and will exacerbate issues of adverse selection for mandatory CJR participants who are impacted by it.

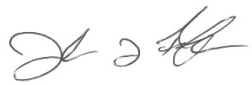
We believe it is inappropriate for CMS to subject CJR participants to potential losses by forcing them to accept insurance risk (as opposed to performance risk) resulting from adverse selection. Therefore, we strongly recommend that CMS continue its U&EC policy until the end of the PHE – even if it extends beyond March 31, 2021. HFMA members believe the policy of capping actual episode payments at the target price determined for that episode for all cases should continue for the remainder of the PHE as a mechanism to protect mandatory CJR participants from adverse selection.

HFMA looks forward to any opportunity to provide additional assistance or comments to CMS to further their efforts to help providers respond to the COVID-19 pandemic. As an organization, we take pride in our long history of providing balanced, objective financial technical expertise to Congress, federal

[3] " 'Non-emergent' procedures 'temporarily rescheduled' at Sanford Health; surgeries continuing at Avera," Keloland News, Nov. 3, 2020.
[4] "Some non-elective procedures pushed back to free up beds for COVID-19 patients," WKOW.com, Oct. 28, 2020.
[5] "Ballad Health hospitals postpone elective procedures amid COVID-19 surge," Modern Healthcare, Oct. 26, 2020.

agencies and advisory groups. If you have additional questions, you may reach me or Richard Gundling, Senior Vice President of HFMA's Washington, DC, office, at (202) 296-2920. The Association and I look forward to working with you.

Sincerely,



Joseph J. Fifer, FHFMA, CPA
President and Chief Executive Officer
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Cc: Brad Smith, Deputy Administrator & Director, Center for Medicare and Medicaid Innovation Center

About HFMA

HFMA is the nation's leading membership organization for more than 56,000 healthcare financial management professionals. Our members are widely diverse, employed by hospitals, integrated delivery systems, managed care organizations, ambulatory and long-term care facilities, physician practices, accounting and consulting firms and insurance companies. Members' positions include chief executive officer, chief financial officer, controller, patient accounts manager, accountant and consultant.

HFMA is a nonpartisan professional practice organization. As part of its education, information and professional development services, HFMA develops and promotes ethical, high-quality healthcare finance practices. HFMA works with a broad cross-section of stakeholders to improve the healthcare industry by identifying and bridging gaps in knowledge, best practices and standards.