



Charles N. Kahn III
President and CEO

December 31, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (CMS-9912-IFC)

Dear Administrator Verma:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care across settings in both urban and rural areas. Our members include teaching and non-teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals. They provide a wide range of acute, post-acute, emergency, children's, cancer care, and ambulatory services. The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) about the above-referenced Interim Final Rule with Comment Period (IFC) regarding implementation of provisions of the Coronavirus Aid, Relief, and Economic Security (CARES) ACT involving coverage for COVID-19 vaccines and other matters.

The FAH is very supportive of the CARES Act provision of coverage for COVID vaccines at no cost to the patient. Uptake of the vaccines is essential to mitigating the effects of the pandemic, including escalating rates of infection and hospitalizations throughout the country. Without achieving maximum rates of vaccination, the devastating effects of the pandemic on the mortality and health of Americans, the entire health care system, and the overall US economy will continue.

A. Medicare Coding and Payment for COVID-19 Vaccine

The IFC implements section 3713 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which provides for Medicare coverage of a COVID-19 vaccine and its administration under Medicare Part B without application of any cost sharing. The Act provides that Medicare coverage for a vaccine is effective on the date the vaccine is licensed by the Food and Drug Administration (FDA) under section 351 of the Public Health Service Act, and the FAH strongly agrees with CMS' determination that for purposes of Medicare coverage and payment, and Emergency Use Authorization issued for a COVID-19 vaccine during the public health emergency is tantamount to a license under section 351. The FAH appreciates that CMS included discussion of its plans for implementing section 3713 in the IFC even though the CARES Act provided it with the authority to implement COVID-19 vaccine coverage through program instruction and without going through notice and comment rulemaking.

Medicare Advantage and Cost Plans

Based on the discussion in the IFC and public statements made by CMS officials, the FAH understands that although Medicare Advantage (MA) plans are generally required to provide enrollees with all Medicare Part B benefits, the COVID-19 vaccines will fall under the exception for new Medicare benefits under §422.109, which provides that new benefits with a significant cost are covered under the fee-for-service Medicare program until the costs are factored into MA payments. As a result, for CYs 2020 and 2021, Medicare payment for the COVID-19 vaccine and its administration for beneficiaries enrolled in MA plans will be made through the original fee-for-service Medicare program. The FAH expects that CMS and the Medicare Administrative Contractors will further clarify in guidance how providers shall bill Medicare fee-for-service for COVID-19 vaccines provided to Medicare beneficiaries enrolled in MA plans. We also encourage CMS to instruct MA plans to educate enrollees that the vaccine will be available for free and need not be obtained through MA network providers.

B. COVID-19 Vaccine Coverage for Medicaid CHIP, and BHP Beneficiaries

The FAH appreciates CMS clarifying current policy related to COVID-19 vaccine coverage for individuals covered under Medicaid, the State Children's Health Insurance Program, and the Basic Health Program. Under section 6008 of the Families First Coronavirus Response Act (FFCRA), states receiving enhanced Medicaid federal matching funds must cover all COVID-19 testing services and treatment, including vaccines and their administration, for Medicaid enrollees without cost sharing. In the IFC, CMS makes clear the circumstances under which those enrollees are eligible for vaccine coverage without any required copayment both during and after the COVID-19 PHE.

We also appreciate CMS identifying the alternative ways that states can modify definitions of covered benefits or covered provider services to ensure continued coverage of vaccines even after the PHE period ends and Section 6008 of the FFCRA is no longer applicable.

Finally, we strongly support CMS' clarification that states must compensate Medicaid providers for vaccine administration or for a provider visit during which a vaccine is administered even if the vaccine is furnished to the provider at no cost.

We are concerned, however, that CMS interprets the FFCRA requirements to not apply to all Medicaid beneficiaries. In particular, CMS states that they do not apply to individuals who are:

- Receiving Medicaid via certain eligibility groups whose benefits are statutorily limited to a narrow range of benefits; for example, those eligible only for family planning services and supplies, for tuberculosis-related services; or
- Covered under state demonstration waivers approved under section 1115 of the Act if those waivers provide for limited benefits for individuals who are not otherwise eligible for Medicaid.

We are concerned that narrowly interpreting the FFCRA provision to omit some of the most vulnerable citizens does not make sense and is not in the spirit of Congressional intent to ensure the maximum access to COVID-19 vaccines for people enrolled in Medicaid.

C. Price Transparency for COVID-19 Diagnostic Tests

The FAH supports HHS's definitions of "diagnostic test for COVID-19" and "provider of a diagnostic test for COVID-19" in 45 C.F.R. § 182.20 and opposes any expansion of the "cash price" disclosure requirements beyond the diagnostic test itself and the furnishing provider. The FAH broadly supports HHS's interest in developing policies that provide patients with accurate and actionable information concerning their cost-sharing exposure. In light of the COVID-19 public health emergency, Congress passed the *Families First Coronavirus Relief Act (FFCRA)* (Pub. L. No. 116-127), which ensures that consumers are financially protected and can use their health care coverage to access COVID-19 diagnostic testing (section 6001(a)(1)) and related items and services that might be provided to determine the need for the invitro diagnostic test during an office or other visit (section 6001(a)(2)) without any cost-sharing obligations. Under Section 3202(b)(1) of the *Coronavirus Aid, Relief, and Economic Security Act (CARES Act)*, Congress also created a cash price requirement that is explicitly confined only to the pricing of the "diagnostic test for COVID-19" by the provider of such test during the public health emergency period. In so doing, Congress did not create a cash price requirement for other related items and services described in section 6001(a)(2) of the *FFCRA* and did not authorize the Secretary to adopt such a requirement. The Final Rule's definition of "COVID-19 diagnostic test" and "provider of a diagnostic test for COVID-19," which exclude related items and services described in section 6001(a)(2) and the provider of such items and services, is thus consistent with the unambiguous statutory language adopting a limited "cash price" requirement. Therefore, the FAH supports the definitions in the Final Rule and would oppose any proposal to expand the "cash price" requirement.

D. Medicare IPPS: New COVID-19 Treatments Add-on Payment

CMS is using its authority under section 1886(d)(5)(I) of the Social Security Act (the Act) to create a new add-on payment (NCTAP) under the Inpatient Prospective Payment System (IPPS) for treatment of certain COVID-19 cases effective November 2, 2020 and continuing for the

duration of the COVID-19 PHE. Hospitals will be eligible for the NCTAP payment if the following conditions are met:

- The patient must be treated with a product approved for inpatient use for patients with COVID-19 (there are currently two products that meet this criteria remdesivir and convalescent plasma);
- The case must also be eligible for the 20 percent increase in the weighting factor for the assigned MS-DRG based on the individual being diagnosed with COVID-19 and discharged from the hospital during the PHE; and
- The operating cost of the case must exceed the operating federal payment under the IPPS, including the 20 percent add-on payment.

If these criteria are met, CMS will pay the hospital the lesser of:

- 65 percent of the operating outlier threshold for the claim; or
- 65 percent of the amount by which the costs of the case exceeds the standard DRG payment, including the 20 percent add-on.

To determine the hospital's IPPS outlier payments, CMS will not consider the NTAP payment. **The FAH agrees with all of these policies.**

E. Medicare OPSS: Separate Payment for New COVID-19 Treatments

Part B therapeutic drugs administered to patients in the outpatient department are separately paid if their per days costs exceed \$130 unless the drugs are billed for a patient assigned to a comprehensive APC (C-APC). In this circumstance, CMS packages payment and does not pay separately for the drug.

The IFC creates an exception under the OPSS to provide for separate payment of certain new COVID-19 treatments during the PHE, should any become available for the outpatient setting, even when billed for a patient assigned to a C-APC. Separate payment will result in the Medicare beneficiary incurring a 20 percent coinsurance payment up to a maximum of \$1,484 (the inpatient deductible) in 2021.

While remdesivir and convalescent plasma are approved to treat COVID-19, they are only approved to treat inpatients. At the time of the IFC, there were no therapeutic drugs approved to treat patients with COVID-19 on an outpatient basis.

Since that time, the FDA has approved bamlanivimab and casirivimab and imdevimab administered together for treatment of COVID-19 on an outpatient basis. CMS is treating these products as vaccines which would allow payment at 95 percent of average wholesale price and the patient to receive the treatment without coinsurance for either the drug or its administration.

The FAH agrees with CMS' policy to pay separately, even under a C-APC, for Part B drugs approved to treat patients with COVID-19 on an outpatient basis. We also agree with CMS' decision to treat bamlanivimab and casirivimab and imdevimab administered together as vaccines. In the final rule FAH requests that CMS make an affirmative statement that

bamlanivimab and casirivimab and imdevimab administered together will always be paid separately in the hospital outpatient department and will not be packaged into a C-APCs (unless the drug is furnished to the hospital at no cost in which case the drugs is not billable).

F. Temporary Increase in Federal Medicaid Funding

Under section 6008 of the FFCRA legislation, states were provided with a temporary 6.2 percentage point increase in their federal Medicaid matching rate through the end of the period in which the public health emergency expires. As a condition of receiving those additional federal funds, state Medicaid programs are not permitted to implement eligibility standards, methodologies or procedures that are more restrictive or charge higher premiums than were in place on January 1, 2020 and they must ensure that individuals enrolled on the date of enactment or during the PHE remain eligible for such benefits through the end of the PHE unless the individual voluntarily requests to terminate their eligibility or they cease to be a resident of the state (the “maintenance of effort” provision.)

The IFC provides a new interpretation of the maintenance of effort provision that provides more flexibility for states to make changes to individuals’ eligibility and coverage of benefits and permits states to drop certain people from Medicaid coverage altogether.

Prior guidance from the administration had ensured continuous Medicaid coverage throughout the PHE. Under that guidance, states could not alter eligibility or enrollment except under the two circumstances identified in the statute: when an individual voluntarily requested termination or is no longer a resident of the state. The new rules permit states to continue to receive their enhanced matching funds even if they:

- Drop enrollees from the program altogether if the enrollees are determined to be “not validly enrolled.” The IFC describes a person who is not validly enrolled as someone erroneously covered either because of error or fraud.
- Move enrollees from one coverage group to another under which they could qualify for fewer Medicaid benefits but only if they retain coverage for vaccines.
- Drop optional benefits.

We are concerned that the new interpretation of the maintenance of effort requirement will result in coverage gaps for some and result in others losing their Medicaid coverage entirely. We believe these flexibilities are contrary to the spirit of the FFCRA legislation which established extra funding for states to ensure the broadest coverage for low-income individuals enrolled in Medicaid during the public health emergency period. We are further concerned that the IFC establishes highly confusing and administratively complicated rules. For example, under the rule, states will have to restart redetermination processes, redetermine eligibility, and move people from one coverage category to another in a manner that is considerably different from traditional Medicaid procedures. Those administrative complexities will need to be implemented by overwhelmed state program employees in the middle of a pandemic.

We understand that this modified interpretation of the maintenance of effort requirement is potentially protective of providers in that it gives states an alternative to cutting provider payment rates in order to reduce program costs. On the other hand, we are concerned that if the rule results

in a considerable loss of coverage, uncompensated care will rise for many health care providers who are already under duress as a result of the pandemic.

G. Updates to the Comprehensive Care for Joint Replacement (CJR) Model, Performance Year (PY) 5 During the COVID-19 Public Health Emergency (PHE)

The FAH appreciates the opportunity to comment about the four changes to the Comprehensive Care for Joint Replacement (CJR) Model as adopted through this IFC (CMS-9912-IFC). We are committed to supporting carefully-crafted initiatives intended to advance patient-centered, value-based care. Many of the Federation’s members are CJR model participants and we continue to follow the model with keen interest. We note our submission of detailed comments earlier this year in response to other CMS rules involving the model, including the proposed 3-year extension of the model (CMS-5529-P) and the changes to the MS-DRGs included in the model that were part of the FY 2021 IPPS proposed rule (CMS-1735-P).

The CJR model was finalized through notice-and-comment rulemaking on November 24, 2015, and the first performance year (PY 1) of the model began on April 1, 2016. The planned end date for this model, in which participation is mandatory for hospitals in 67 metropolitan statistical areas (MSAs), was designed to end with the conclusion of PY 5 on December 31, 2020. The design of the model underwent significant revision, finalized on December 1, 2017, as part of CMS-5524-F and IFC, including reduction of the number of mandatory-participation MSAs from 67 to 34 and addition of a model-specific policy for extreme and uncontrollable circumstances exceptions (ECE).¹ On February 24, 2020, CMS published a proposed rule to extend the model for an additional three performance years (PYs 6-8) to begin January 1, 2021, with continued mandatory participation by hospitals in 34 MSAs (85 FR 10516). The proposed rule also would make substantive changes to the financial and quality terms of the model that are, in general, stricter than the model’s original parameters. The rule’s comment period ended April 24, 2020, and the rule has not yet been finalized. In what CMS refers to as the “April 2020 IFC”, PY 5 was extended through March 31, 2021. That IFC also made the ECE policy applicable to CJR episodes occurring through the termination of the COVID-19 public health emergency (PHE), so that actual episode expenditures are equal to the target price, effectively eliminating downside risk for those episodes.

The current IFC, published in the Federal Register for November 6, 2020, makes four changes to the CJR model:

- Extending performance year 5 an additional 6 months through September 30, 2021;
- Changing the reconciliation process for PY 5 to accommodate the new model end date by splitting PY 5 into two “subset” performance years;
- As a “technical” change, adding two new MS-DRGs to the definition of a CJR model episode retroactive to October 1, 2020; and
- Revising the ECE for the COVID-19 PHE to set a finite date for the end of downside risk elimination other than for episodes that explicitly carry a COVID-19 diagnosis.

¹ The interim rule’s ECE policy was finalized and published in the June 28, 2018 Federal Register (83 FR 26604).

1. **Extend PY 5 through 9/30/2021**

Through this IFC, PY 5 of the CJR model is extended for a further six months through September 30, 2021, or nine months beyond its originally-designed model end date. CMS states that the extension will “provide for continuity of model operations with the same scope while we continue to consider comments received on our proposal to extend the model to performance years 6 through 8”. The agency simultaneously explicitly seeks comment about two options for the duration of the proposed PYs 6-8 that vary the PY duration but both begin on October 1, 2021. **The Federation does not have a strong preference for either options presented for the durations of PY 6-8;** however, we note that CMS appears to be signaling an intent to finalize the proposed CJR 3-year extension.

Like the extension of PY 5 of the CJR model to March 31, 2020, accomplished earlier this year via an IFC, **the Federation finds further extension of PY 5, now through September 30, 2021, to be untenable.** We base our position first and foremost on the widespread, ongoing, highly disruptive effects on healthcare of the COVID-19 PHE. COVID-19 cases are surging, reaching levels near or above those seen in the early months of the pandemic. Hospitals are invoking their surge policies. Significant activity restrictions are being reinstated in many communities. Elective operations are once again being limited in many facilities and by many surgeons. Patients are fearful of entering healthcare facilities and deferring needed care, not just elective operations. Their willingness to enter post-acute care facilities, as often occurs after CJR operations, is low. Post-acute care beds are being diverted to deliver acute care for COVID-19 and home health resources are being seriously stretched.

Even with the recent approval of two vaccines, considerable time will be required to vaccinate enough individuals to significantly slow the spread of the disease. Further, the duration of the protection offered by the vaccine remains uncertain at this time. Full and confident resumption of normal health care operations that would allow performance of major, elective surgical procedures such as TKA and THA to return to pre-COVID levels is not yet on the horizon and will depend on many factors beyond CJR hospitals’ control, such as reliable availability of large amounts of high-quality personal protective equipment that can be allotted for elective procedures. The FAH acknowledges that the operative volume data provided by CMS in the IFC appears to show a partial resumption of TKA and THA over the summer of 2020. We observe, however, that there is an irreducible number of episodes being triggered by THA when performed for fracture treatment, and the end date of the data before the current and substantial surge of COVID-19 cases began.

In addition to the many real-world clinical care considerations described above, further extension of the CJR model seems ill-advised as it would appear to deliver little added benefit to the Medicare program and its beneficiaries beyond what has accrued during PYs 1-4 of the model. All data generated during calendar year 2020 will be suspect, given the known and as yet unknown impacts of the COVID-19 PHE on healthcare delivery patterns. There has been a hiatus in the reporting of quality data by hospitals related to reporting exceptions issued earlier this year. While these exceptions were very appropriate to the time period in which they were issued, the data for this year will be incomplete and compromised, further exacerbating the known limitations of the CJR model quality measure set that we have described in detail in prior comment letters. COVID-related impacts on hospital staffing continue to limit quality data collection. The degraded quality

data will create adverse financial consequences for participant hospitals since quality scores modify shared savings calculations. The Federation believes that it would be difficult, if not impossible, to generalize any reliable findings for the future from CJR 2020 data and we believe that it would be quite unfair to use 2020 results to evaluate the performance of any CJR hospital.

Formal evaluation of the CJR model will be seriously confounded if 2020 data are included. CMS has accrued four years of data that, combined with those from the BPCI joint replacement episodes, presumably already could allow meaningful conclusions about bundled arthroplasty costs and quality. Additional relevant data could be generated by ending the CJR model and creating a simple streamlined pathway by which a CJR hospital could voluntarily become an Episode Initiator (non-convenor participant) for the BPCI-Advanced site-neutral lower extremity joint replacement episode that is already underway.

The FAH opposes further extension of the CJR model. Further we strongly recommend that if CMS persists in its desire to extend the model, any extension of the CJR model should be as a voluntary rather than mandatory model.

2. Revising PY 5 Reconciliation

As noted in the IFC, extending the CJR model through September 2021 creates a prolonged PY 5, lasting 21 months, and a similarly long interval from the final reconciliation for PY 4 (June 2020) to the initial reconciliation for PY 5 (February 2022). The length of this performance year falls well outside the design parameters of the CJR model and brings with it myriad operational questions for CJR participants (e.g., when will reconciliation occur) that are made even more numerous and more complex by the ongoing COVID-19 public health emergency (PHE).

To address some of the operational issues of the prolonged PY 5, through this IFC CMS is implementing a “split” PY 5 for purposes of reconciliation: subset PY 5.1 running from January through December 2020 and subset PY 5.2 running from January through September 2021. Each subset PY would have initial and final reconciliations (the very last of which would occur in February 2023) and separately calculated composite quality scores. Quality scoring of CJR participants will exclude those months for which CMS issued a waiver creating exemptions from hospital quality reporting programs.²

The Federation takes a bifurcated view of the revised PY 5 reconciliation process described in this IFC. From an operational perspective, the split PY 5 appears to be one potentially acceptable approach to the problem of a markedly prolonged PY 5 that has been created by CMS’ two extensions of the CJR PY 5 (initially through March 2021 and now through September 2021). PY subset 5.1 partially mimics a “normal”, pre-COVID 12-month performance year and PY subset 5.2. We do have some concerns about this approach: it is complex and CJR participant hospitals will be challenged to determine accurately how they are performing under the model (financial results and quality outcomes) in any semblance of “real-time”. **However, the FAH is not strongly opposed to the split PY 5 approach as a solution to the operational issues inherent in the 21-month performance year.**

² <https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf>

From a conceptual perspective, however, the Federation does not support the split PY 5 approach to reconciliation. The prolonged performance year problem has been created by CMS' insistence at continuing the CJR model not only through its pre-COVID scheduled endpoint (December 31, 2020) but for an additional 9 months. While CMS cites its wish to avoid disruption to the testing of the CJR model, we would observe that the model already has been markedly, though unintentionally, disrupted by the pandemic. This is borne out by the volatility of the CJR episode volume as provided in Table 1 of this IFC, data that are highly unlikely to have reached a steady state during subsequent months during which COVID-19 cases have surged to levels seen in the earliest months of the pandemic. **The FAH strongly believes that the best solution available to bring about true stability of the CJR model is to reinstate its original planned end date of December 31, 2020, creating a 12-month PY 5 in which the extreme and unusual circumstances applies for the entire period** (actual episode expenditures are capped at the target price). Given the limited time available to implement this solution, the Federation would regard reinstating the initial extension through March 2021 as the next best alternative. The 15-month performance period thus created for PY 5 is operationally manageable as a single unit that does not require the complex split PY 5 outlined in this IFC.

The FAH questions why there is any need to prolong PY 5 through September 2021. There are no clear benefits to the participant hospitals. CMS does not identify benefits to the agency or to the model other than restoring some possibility of net savings to the Medicare program for PY 5 if the pandemic is resolved early in CY 2021. An additional benefit described by CMS is assuring continuous operation of the model until the proposed 3-year extension (PYs 6-8) would start. We note that a final rule concerning the 3-year CJR extension has not been published nor does it yet appear to be under review at OMB.

The Federation understands that CMS has had to concentrate most of its attention on responses to the acute challenges of the pandemic but avoiding a decision whether to proceed with the 3-year CJR extension is creating substantial disruption and frustration for the current CJR hospitals that would be forced to continue to participate in any extension of this mandatory model. The comment period on the proposed rule for the extension ended April 24, 2020, and CMS has indicated several times since that review of those comments was underway. CMS has accomplished a great deal in regard to responding to the pandemic in the interval since the comment period closed, thus demonstrating remarkable and rapid decision-making capabilities that seemingly could similarly be applied now to the proposed CJR extension.

The Federation, therefore, recommends that CMS move forward with its decision as to whether or not it remains in the best interests of Medicare beneficiaries to extend the CJR model as proposed. We note our extensive comments previously submitted to CMS in which we opposed mandatory model extension are readily available at https://www.fah.org/fah-ee2-uploads/website/documents/CJR_Extension_FAH_Comments_62320.pdf

3. Adding New Hip Fracture MS-DRGs 521 and 522

CMS is retroactively adding two new MS-DRGs to the CJR model episode definition as of October 1, 2020: 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*. Admissions under these new MS-DRGs

previously mapped to MS-DRGs 469 and 470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC and without MCC, respectively), then were subdivided within each MS-DRG by presence or absence of hip fracture. CMS is also incorporating the new MS-DRGs and their respective weights into the quality-adjusted target prices for the remainder of PY 5.

The new MS-DRGs were finalized during FY 2021 IPPS rulemaking. In commenting on the FY 2021 IPPS proposed rule, the FAH expressed conceptual support for recognizing the increased costs of hip replacement when used for fracture treatment by creating the new MS-DRGs. However, we also voiced concerns about the face validity of their relative weights, given the apparent misalignment of those weights with the associated geometric mean length-of-stay data provided by CMS. In the IPPS final rule, CMS adopted the weights as proposed but stated an intent to incorporate the new MDS-DRGs into the CJR model as part of a future final rule concerning the proposed 3-year CJR model extension.

The Federation remains concerned about the accuracy of the relative weights of MS-DRGs 521 and 522. Further, we are troubled that CMS is advancing the timeline for their incorporation into the CJR model episode definition and target price calculations to become effective now for PY 5. CMS offers no clear rationale for hastening implementation and does not refer to relevant comments already received in response to the proposed CJR extension, comments that have been available since April 24, 2020. The FAH believes that CJR model participants and the beneficiaries for whom they are caring would be better served by further consideration of the MS-DRG changes and their impacts, as would be allowed by following the previously announced PY 6 implementation timeline. Deliberate rather than hasty consideration, including review of comments received in response to the proposed CJR extension and assessment of the accuracy and generalizability of 2020 claims data for rate-setting purposes, seems particularly appropriate in the context of the ongoing and substantial instability of the health care delivery ecosystem during the COVID-19 PHE.

However, CMS indicates that assigning episodes to these new MS-DRGs has already begun (October 2020). CMS further describes the addition as seamless for hospitals and of minimal financial impact. The Federation is uncertain about the extent of the impact since we have insufficient information to confirm CMS' conclusion. We note that a decision not to finalize the proposed 3-year CJR extension or to terminate PY 5 March 31, 2021, as we have recommended, would in fact limit the financial impact since the new MS-DRGs would only be applied for a short time (October through December 2020 or through March 2021). **The FAH strongly suggests that CMS monitor the episodes mapped to the new MS-DRGs and conduct periodic data analyses to ascertain the actual financial impact of the MS-DRG additions to the CJR model.**

4. Modifying CJR ECE Policy

The Federation greatly appreciates CMS' rapid invocation and broad application of the CJR ECE policy. As a result, our member hospitals and their clinicians and staff have been freed up to focus their attention on the enormous clinical demands facing them and on the delivery of the best possible care under extraordinary circumstances. Further, the possibility, though perhaps quite small, of receiving shared savings is still valuable as hospital finances continue to be seriously stressed by the pandemic.

We are disturbed, however, by CMS acting now to set a time certain (March 31, 2021) at which the elimination of downside risk for CJR participants will end. Given the ongoing surge of COVID-19 cases and the many consequences thereof, this action seems premature. Even under the best-case scenario for vaccine production, distribution, efficacy, and safety, the full impact of any vaccine will not be felt for many months, and the available disease treatments, while improved since early in the pandemic, remain suboptimal. CMS cites the operative volume data provided in this IFC, but we note again that these data include an irreducible number of hip arthroplasties for fracture treatment, the numbers are volatile, and the data do not reflect the pandemic's resurgence.

The FAH appreciates CMS' decision to continue to apply the ECE policy after March 31, 2021 at least to CJR episodes "during which a CJR beneficiary receives a positive COVID-19 diagnosis". While CMS allows for a variety of diagnostic codes by which a COVID-19 diagnosis could be established, we know from our members that consistent and reliable COVID coding has been difficult to achieve. Also, we are unclear at what point in the CJR episode the COVID diagnosis would need to occur for the ECE policy to be invoked, which could be of substantial importance in the application of this policy during a bundle of care lasting a minimum of 91 days. Further, does this policy imply that every CJR patient should be tested on the date of the anchor hospitalization? and perhaps periodically throughout the episode of care? The regulatory complexity that may be required to administer what CMS terms a "targeted adjustment" may negate the benefit of this approach.

The Federation strongly objects to setting a time certain to end broad application of the CJR ECE policy. Further, if CMS persists with this approach, we ask that the requirements for establishing a COVID-19 diagnosis be simple and clear-cut, such as a diagnosis made within 30 days prior to the anchor hospitalization though the entire postoperative 90-day bundled period plus 14 days.

In summary, the Federation has significant concerns about each of the four provision for changes to the CJR model contained within the current IFC. We recommend that CMS end the model expeditiously and rescind its plan to end broad application of the CJR ECE policy on March 31, 2021.

The FAH appreciates the opportunity to comment on the proposed rule. If you have any questions, please contact me or a member of my staff at 202-624-1534.

Sincerely,

