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

Summary of Interim Final Rule with Comment Period
CMS-9912-IFC

On November 2, 2020, an interim final rule with comment period (IFC) providing for additional policy and regulatory revisions in response to the COVID-19 public health emergency (PHE) was posted for public inspection. The IFC contains provisions of the Centers for Medicare & Medicaid Services (CMS) and the Departments of Treasury, Labor, and Health and Human Services (HHS), referenced as "the Departments." The rule is scheduled for publication in the *Federal Register* on November 6, 2020.

The IFC establishes coverage of a COVID-19 vaccine without cost sharing under Medicare, Medicaid, the Children's Health Insurance Program (CHIP), the Basic Health Program (BHP), and private plans, specifically non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance. Price transparency rules are established for COVID-19 diagnostic tests. Special payment rules are established for new COVID-19 treatments under Medicare for the acute inpatient hospital and outpatient hospital settings. Conditions for receiving temporarily increased federal matching payments under Medicaid are modified. Medicare's Comprehensive Care for Joint Replacement (CJR) model is extended. Flexibilities are provided with respect to public notice requirements and post-award public participation requirements for State Innovation Waivers during the COVID-19 PHE.

With a few exceptions noted in the summary, provisions of the IFC will be effective from November 2, 2020 through the end of the COVID-19 PHE. **The public comment period closes on January 4, 2021.**

TABLE OF CONTENTS

I.	Background	2
II.	CMS Provisions	2
	A. Medicare Coding and Payment for COVID-19 Vaccine	2
	B. COVID-19 Vaccine Coverage for Medicaid, CHIP, and BHP Beneficiaries	6
	C. Price Transparency for COVID-19 Diagnostic Tests	8
	D. Medicare IPPS: New COVID-19 Treatments Add-on Payment (NCTAP)	13
	E. Medicare OPPS: Separate Payment for New COVID–19 Treatments	17
	F. Temporary Increase in Federal Medicaid Funding	18
	G. Updates to the CJR Model, Performance Year 5 During the PHE	21
III.	Treasury/ Labor/HHS – Rapid Coverage Coronavirus Preventive Services	25
IV.	Treasury/Labor/HHS – State Innovation Waivers	28
V.	Waivers of Proposed Rulemaking	29
VI.	Regulatory Impact Analysis	31

I. Background

On January 31, 2020, the Secretary of HHS declared a Public Health Emergency (PHE) for the "coronavirus disease 2019" (known as COVID-19) for the U.S. retroactive to January 27, 2020; the PHE was renewed on April 26, 2020, July 23, 2020, and most recently on October 23, 2020. On March 11, 2020, the World Health Organization (WHO) declared the COVID-19 outbreak as a pandemic, and on March 13, 2020, the President declared the COVID-19 outbreak a national emergency retroactive to March 1, 2020.

Three IFCs previously issued by CMS also addressed policies pertaining to the COVID-19 PHE. These are "Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (85 FR 19230), effective on March 31, 2020; "Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program" (85 FR 27550), effective on May 8, 2020; and "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments, and Patient Protection and Affordable Care Act: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (85 FR 54820), effective on September 2, 2020.

II. CMS Provisions

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 amends section 1861(s)(10)(A) of the Social Security Act to provide Medicare coverage of a COVID-19 vaccine and its administration under Medicare Part B without application of any cost sharing. (Pneumococcal, influenza, and hepatitis B virus (HBV) vaccines are similarly covered under this section.) CMS notes that the CARES Act allows it to implement this provision without notice and comment rulemaking (i.e., "through program instruction or otherwise"). However, the agency believes it best to clarify its interpretation of the provision and inform the public of its plans for coverage and payment of a COVID-19 vaccine once licensed by the Food and Drug Administration under section 351 of the Public Health Service (PHS) Act. It intends to issue program guidance as needed to ensure that Medicare beneficiaries have access to a vaccine as quickly as possible.

1. Background on Medicare Part B Payment, Coding, and Billing for Vaccines

Medicare payment for the covered vaccines is limited to 95 percent of the average wholesale price (AWP), except that when furnished by a hospital outpatient department, rural health clinic, federally qualified health center, skilled nursing facility, or home health agency payment is based on reasonable cost. CMS offers the example that for the 2020-2021 influenza season, the payment limits for adult flu vaccines range from $19 to $61 per adult dose[1]. [In a conference call discussing this IFC on October 30, 2020, CMS clarified that the federal government will be

[1] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/VaccinesPricing

financing COVID-19 vaccines, and as a result this provision of the IFC applies only to the cost of vaccine administration.]

Providers and suppliers generally bill for the vaccine and its administration separately using different codes. CMS explains that many vaccine products are identified by AMA CPT codes in the 90000 series, while others are identified by Level II HCPCS codes, usually beginning with the letter Q. Vaccine administration services are described by the types of codes used for professional and/or hospital outpatient services, and are typically identified by a G code for Medicare billing, or by a different AMA CPT code in the 90000 series.

In addition to these usual billing approaches, Medicare offers enrollment of entities as "mass immunizers" to provide influenza and pneumococcal vaccines to large groups of Medicare beneficiaries under roster billing. Mass immunizers may submit claims for immunizations (vaccine and administration) on roster bills that include a limited set of information on each beneficiary and the vaccine(s) they were given. (Because HBV vaccines require an assessment of a patient's risk of contracting hepatitis B, they require a physician's order and cannot be roster billed by mass immunizers.)

Mass immunizers include entities already enrolled in Medicare as providers and suppliers (e.g., physician, non-physician practitioner, hospital outpatient department, home health agency or skilled nursing facility) but also includes entities or individuals who enroll only to furnish mass immunization services.[2] The latter must meet certain Medicare enrollment requirements and applicable state and local licensure or certification requirements, and must limit their Medicare billing to the specified vaccine services and submit claims through the roster biller or centralized biller process.

CMS notes that the upcoming final rules for Medicare Payment in 2021 under the Physician Fee Schedule and the Hospital Outpatient Prospective Payment System will establish payment rates for the administration of covered vaccines.

In the Collection of Information Requirements section of the IFC, CMS estimates that 60,000 entities (primarily pharmacies) will seek to enroll as mass immunization roster billers within 12 months following issuance of the IFC. The cost of enrollment is estimated to be $122.50 per entity, or $7.35 million in the aggregate. CMS notes that based on past experience it expects few denials or revocations of mass immunizer roster biller enrollments.

2. Emergency Use Authorization for Vaccines to Prevent COVID-19

Section 3713(d) of the CARES Act provides that Medicare coverage of a COVID-19 vaccine is effective on the date the vaccine is licensed by the FDA under section 351 of the PHS Act, and CMS discusses the potential for emergency use authorization (EUA) of COVID-19 vaccines under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). It notes that there

[2] These providers may enroll in the Medicare as a "Mass Immunization Roster Biller" via the Form CMS-855 enrollment application (Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers; OMB Control No.: 0938-0685; Expires 12/21).

are no precedents for Medicare coverage of a vaccine product for which an EUA was issued by FDA.

CMS concludes that for purposes of Medicare coverage and payment, it is appropriate to consider an EUA issued for a COVID-19 vaccine during the PHE to be tantamount to a license under section 351 of the PHS Act. CMS bases this decision on recognition that many Medicare beneficiaries fall under the categories identified by the Centers for Disease Control and Prevention (CDC) as high-risk for severe illness from COVID-19,[3] the circumstances of the nationwide pandemic, and FDA's guidance indicating that an EUA may be appropriate for COVID-19 vaccines.[4] Among other requirements, that guidance states that issuance of an EUA would "require a determination by FDA that the vaccine's benefits outweigh its risks based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner." CMS states that because the vaccine is designed for a healthy population there should be greater certainty about the risks and benefits than is needed for an EUA for products treating sick patients.

CMS believes that its interpretation of section 3713(d) of the CARES Act is consistent with Congressional general intent to provide for rapid coverage of COVID-19 vaccines, and its specific intent for Medicare coverage, without deductible or coinsurance, of any COVID-19 vaccine that FDA authorizes for introduction into interstate commerce, which would apply to both EUAs as well as licensed vaccines.

3. Implementation of Coding and Payment for a COVID-19 Vaccine and Administration.

Noting that many product-specific factors are unknown at this time, CMS discusses its plans for quick implementation of coding and payment for COVID-19 vaccines and administration under Medicare Part B. The CARES Act provision adding Part B coverage of COVID-19 vaccines and administration establishes the allowed amount for the vaccine at 95 percent of the AWP, or reasonable cost, as applies to payment for other covered vaccines (i.e., influenza, pneumococcal, and HBV vaccines).

CMS anticipates the possibility of differential costs associated with each COVID-19 vaccine product and its storage and administration requirements, and therefore plans to establish a unique administration code for each COVID-19 vaccine product. Specific coding and payment rates would be established through technical direction to the Medicare Administrative Contractors (MACs). Information on coding, payment, and billing would be made public by the MACs and on the CMS website. CMS expects that payment rates for administration of other Part B preventive vaccines and related services, such as the flu and pneumococcal vaccines, would inform the payment rates for administration of COVID-19 vaccines.

---

[3] CMS cites in particular that higher-risk categories include older adults, with risk increasing by age; people with serious chronic medical conditions such as obesity, cardiovascular disease, diabetes, hypertension, chronic lung disease, and neurologic/neurodevelopmental disability; immunocompromised individuals; and residents of long-term care facilities. Readers are directed to https://www.cdc.gov/mmwr/volumes/69/wr/mm6913e2.htm.
[4] FDA. Emergency Use Authorization for Vaccines to Prevent COVID-19. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19

To expedite beneficiary access to COVID-19 vaccines, as soon as practicable after authorization or licensure of each COVID-19 vaccine product by the FDA, CMS plans to announce the interim coding and payment rate for administration (or, for the Hospital Outpatient Prospective Payment System (OPPS), an Ambulatory Payment Classification (APC) assignment for each vaccine product's administration code). The rates will consider any product-specific costs or considerations involved in furnishing the service in order to ensure that providers can offer prompt access to vaccination for a large number of people as quickly as possible. CMS would then address these coding and payment rates for administration of the COVID-19 vaccine products through future notice-and-comment rulemaking.

With respect to billing, CMS believes it would be appropriate to use processes for COVID-19 vaccinations that are similar to those already in place for flu and pneumococcal vaccinations. In particular, given the need for broad access to COVID-19 vaccine, it believes the mass immunization and roster billing process would be appropriate. There is limited information at this time on the COVID-19 vaccines and their administration, but CMS currently understands that the vaccines will be administered as one or two parenteral doses. Although the flu vaccine is generally provided as one dose per flu season, CMS says that it has contemplated situations requiring administration of multiple doses. Therefore, it believes that using the Part B influenza vaccine approach can accommodate a two-dose initial COVID-19 vaccination schedule. CMS anticipates that as information about vaccine products becomes available, updated information would be disseminated primarily by program instruction. This would include information such as additional doses after initial vaccination, applicability of specific vaccine products to subsets of the beneficiary population, or updates about billing.

To reflect the IFC policies, CMS is updating the regulatory text in the following places to make appropriate references to COVID-19 vaccine:

- §410.57, Pneumococcal vaccine and flu vaccine
- §410.152(l)(1), Amounts of payment
- §410.160 (b)(2), Part B annual deductible
- §411.15(e), Particular services excluded from coverage
- §414.701, Purpose
- §414.707(a)(2)(iii), Basis of payment
- §414.900(b)(3), Basis and scope
- §414.904(e)(1), Average sales price as the basis for payment

4. Medicare Advantage and Cost Plans

Medicare Advantage (MA) plans and cost plan organizations under section 1876 must cover all benefits under Medicare Parts A and B, with certain exceptions; this includes coverage of a COVID-19 vaccine and its administration as provided in section 1861(s)(10)(A). The statute (as amended by the CARES Act) also prohibits an MA plan from imposing cost sharing for a COVID-19 vaccine and its administration. As discussed above, this IFC provides for Part B coverage of a COVID-19 vaccine for which the FDA issues an EUA during the public health emergency, including administration of such a vaccine consistent with the EUA.

When a new Medicare benefit with significant cost is added through legislation or a National Coverage Determination, an MA organization is not required to assume risk for the costs of that service or benefit until the contract year for which payments are appropriately adjusted to take into account the cost of the benefits. In that case, coverage of the new benefit for MA enrollees is provided through the Medicare fee-for-service program until the MA payments reflect the cost of the benefit. MA payment rates for 2020 and 2021 do not reflect the cost of a COVID-19 vaccine. Under the process established at §422.109, if the CMS Chief Actuary determines that the estimated cost of the benefit represents at least 0.1 percent of the national average per capita costs, or if the average cost of furnishing a single service exceeds a cost threshold established by formula, it is considered a significant cost and the FFS Medicare program provides coverage for the service until the costs are factored into Medicare Advantage payments. CMS estimates that for the COVID-19 vaccine, the significant cost threshold will be met if the projected cost per-beneficiary-per-year is greater than approximately $13 (0.1 percent 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 without cost sharing, at any participating FFS provider or supplier eligible to bill under Part B for vaccine administration. [In a conference call on October 30, 2020 discussing this IFC, Administrator Verma stated that the cost of administering the COVID-19 vaccine to MA enrollees would be borne by fee-for-service Medicare, suggesting that the cost question has been resolved since the IFC was prepared.]

Under the CARES Act amendments providing for COVID-19 vaccine coverage, cost plans are required to cover the COVID-19 vaccine and its administration, but they are not required to provide this benefit without cost sharing when the services are furnished by an in-network provider. Although cost plan enrollees can seek services out-of-network from Medicare fee-for-service providers and no cost sharing would apply to a COVID-19 vaccine obtained in this way, CMS believes that these enrollees may naturally seek the vaccine from their regular in-network provider. Therefore, CMS is using its authority under section 1876(i)(3)(D) to impose other terms and conditions it deems "necessary and appropriate" to require that cost plans comply with the same cost sharing protections for its enrollees that are provided to fee-for-service beneficiaries and MA enrollees. It believes this action is necessary and appropriate to ensure that cost is not a barrier to accessing a COVID-19 vaccine, particularly during the public health emergency. To accomplish this, the IFC adds new regulatory text at §417.454 (e)(4) to require section 1876 cost plans to cover the COVID-19 vaccine and its administration without cost sharing for the duration of the COVID-19 PHE.

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

CMS does not make any changes to current policy or regulations, but clarifies current policy with respect to COVID-19 vaccine coverage for Medicaid, Children's Health Insurance Program (CHIP), and Basic Health Program (BHP) beneficiaries – including both during the PHE as well as after the PHE ends.

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. The enhanced funding is available through the end of the quarter in which the PHE for COVID-19 ends. CMS clarifies that:

(1) Zero cost sharing for those services must continue through the end of the quarter in which the PHE for COVID-19 ends.
(2) 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.
(3) The FFCRA requirements do not apply to all Medicaid beneficiaries. They do not apply to certain Medicaid 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, and those identified under the CARES Act as eligible only for COVID-19 testing. FFCRA also does not apply to beneficiaries 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. States may seek modifications to demonstration coverage to add such benefits, however, and individuals who are uninsured with respect to such vaccines and vaccine administration costs may be eligible to have their claims reimbursed under 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).

CMS also clarifies requirements related to the coverage that would apply when section 6008 is no longer in effect in a state.

(1) All Medicaid children under the age of 21 and adults covered under the Affordable Care Act's (ACA) Medicaid expansion[5] must receive all ACIP-recommended vaccines – in almost all cases they must be provided without cost sharing.
(2) States can receive a 1 percent enhanced matching payment for the costs of certain services in return for covering ACIP-recommended vaccines and their administration without cost-sharing for adults under section 1905(a)(13) of the Act (a provision of law permitting states to define "other diagnostic, screening, preventive and rehabilitation services" as optional benefits.)
(3) Other children may receive their ACIP-recommended vaccines through the Vaccines for Children program.
(4) States have the option to cover the vaccine and its administration for other eligibility groups including coverage for parents and caretaker relatives, elderly adults, and pregnant women. Cost sharing may be charged except with respect to certain groups that are statutorily exempt from cost sharing – including most children and pregnant women, for example.
(5) States can also cover the COVID-19 vaccine as part of its mandatory coverage for certain provider services. For example, the coverage of certain hospitals, physicians, Federally Qualified Health Centers, and Rural Health Clinics is required, and states could reimburse for the administration of a vaccine by those providers as mandatory coverage of that provider's services.

CMS further clarifies that even though FFCRA section 6008 does not apply to separate state CHIP programs or to BHPs, under existing law and regulations states must cover ACIP-

[5] The ACA provided states with the option of extending Medicaid coverage to adults not otherwise eligible for the program whose income is below 138 percent of the federal poverty level.

recommended vaccines and their administration for all children under age 19 without cost sharing under CHIP and for all individuals covered under BHP. Under BHP, states must also cover "qualifying coronavirus preventive services" including a COVID vaccine without cost sharing whether delivered by an in-network or out-of-network provider.

C. Price Transparency for COVID-19 Diagnostic Tests

Key statutory provisions aimed at reducing financial barriers to COVID testing are reviewed. Under section 6001 of the FFCRA, group health plans and health insurance issuers offering group or individual health insurance coverage must cover certain items and services, including COVID-19 diagnostic tests[6] furnished on or after March 18, 2020, and during the COVID-19 PHE. These services must be covered without imposition of any cost-sharing (including deductibles, copayments, and coinsurance) or prior authorization or other medical management requirements. Section 3201 of the CARES Act later amended section 6001 of the FFCRA to include a broader range of diagnostic tests. Section 3202(a) of the CARES Act requires group health plans to reimburse providers of diagnostic testing services an amount that equals the negotiated rate, or, if the plan or issuer does not have a negotiated rate with the provider, the cash price for such service that is listed by the provider on a public website. The plan or issuer may also negotiate a rate with the provider that is lower than the cash price.[7] CMS notes that the reimbursement requirements under CARES Act section 3202(a) will apply to COVID-19 diagnostic testing, as defined in this IFC. The COVID-19 Claims Reimbursement program reimburses eligible providers for the testing and treatment of COVID-19 for certain uninsured individuals. In addition, HHS has partnered with pharmacies, retail companies, and health centers nationwide to make no-cost COVID-19 diagnostic testing available to Americans in communities across the country.

This IFC implements section 3202(b) of the CARES Act, which requires that providers of diagnostic tests for COVID-19 make public on the internet their cash price for such tests during the PHE. The Secretary may impose a civil monetary penalty on any provider of a diagnostic test for COVID-19 that does not comply with this requirement and that has not completed a corrective action plan to comply with that section. The amount of the penalty must not exceed $300 per day that the violation is ongoing.

Regulations are established at new 45 CFR Part 182, "Price Transparency for COVID-19 Diagnostic Tests." The new regulations define key terms, establish requirements for publication of cash prices, and set forth penalties for non-compliance. Further, the IFC describes procedures for monitoring compliance with and enforcement of these requirements.

---

[6] COVID-10 diagnostic tests include *in vitro* diagnostic testing products for the detection of SARS-CoV-2, the virus that causes COVID-19, or the diagnosis of COVID-19. (Footnote 7 below furthers describes *in vitro* testing.) Related items and services that must be covered include those provided during urgent care center visits, in-person and telehealth office visits, and emergency room visits that result in an order for or administration of an in vitro diagnostic product, to the extent that such items and services relate to the furnishing or administration of a COVID-19 diagnostic test, or to the evaluation of an individual for purposes of determining the need of the individual for a COVID-19 diagnostic test.

[7] For more information readers are referred to: https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf and https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf

1. Definitions (§182.20)

- Diagnostic test for COVID-19 ("COVID-19 diagnostic test") is defined as a COVID-19 *in vitro* diagnostic test described in section 6001 of the Families First Coronavirus Response Act, as amended by section 3201 of the CARES Act.[8] **Comments are specifically sought on this definition.** CMS notes that COVID-19 diagnostic tests are currently billed by providers using HCPCS and CPT codes including CPT codes 86408, 86409, 87635, 87426, 86328, and 86769 and HCPCS codes U0001 through U0004. The list is not meant to be exclusive; CMS anticipates updating the list of codes in guidance as new tests and codes are developed.
- Provider of a diagnostic test for COVID-19 is defined as any facility that performs one or more COVID-19 diagnostic tests. CMS notes that in order to perform COVID-19 testing, a facility is required to hold a Clinical Laboratory Improvement Amendments (CLIA) certificate, and it expects that testing would occur in facilities raging from primary care provider offices to stand-alone national laboratories.
- Cash price means the charge that applies to an individual who pays in cash (or cash equivalent) for a COVID-19 diagnostic test. CMS notes that this is generally analogous to the "discounted cash price" defined for purposes of the Hospital Price Transparency final rule at 45 CFR 180.20, or the "walk-in" rate that hospitals apply to self-pay individuals. These prices are often lower than the rate hospitals negotiate with third party payers because self-pay individuals would not require administrative functions such as prior authorization. CMS does not believe that posting a cash price should prevent a provider from offering free testing to individuals as charity care or as a matter of public health; the posted cash price would be the maximum charge to self-pay individuals paying out-of-pocket. **Comments are solicited on whether additional standards should be implemented to address potential abuse.**

Comments are sought on whether the definition of provider of a COVID-19 diagnostic test should be expanded to include providers that perform additional services related to the performance of a COVID-19 diagnostic test, such as for specimen collection or mileage fees that may be billed as part of or in conjunction with specimen collection. CMS asks whether the consumer would benefit from knowing the total cost of care for receiving a COVID-19 diagnostic test, including the doctor's visit and specimen collection. Of particular interest are submissions from stakeholders that include claims-based or anecdotal data on the ways in which consumers request and receive COVID-19 diagnostic testing including the site of care, frequency, and type of provider.

[8] Under section 6001 of the FFCRA as amended and as explained in guidance issued by the Departments, COVID-19 diagnostic tests include all *in vitro* diagnostic tests for the detection of SARS-CoV-2 or diagnosis of COVID-19 provided that a test: (1) is approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the FD&C Act; (2) the developer has requested, or intends to request, emergency use authorization under section 564 of the FD&C Act, unless and until the emergency use authorization request under such section 564 has been denied or the developer of such test does not submit a request under such section within a reasonable timeframe; (3) is developed in and authorized by a state that has notified the Secretary of HHS of its intention to review tests intended to diagnose COVID-19; or (4) is a test that the Secretary of HHS determines appropriate in guidance. *In vitro* diagnostic tests include molecular (RT-PCR) tests, which detect the virus's genetic material; antigen tests, which detect specific proteins on the surface of the virus; and serology testing, which looks for the presence of antibodies produced by the body in response to infections.

2. Requirements for Publication of Cash Prices During the COVID-19 PHE (§182.40)

The requirements for public disclosure of cash prices by a provider of a diagnostic test for COVID-19 are effective during the COVID-19 PHE that began on January 27, 2020. The specific requirements set forth in the IFC are that the provider make at least the following information available to the public electronically via the internet:

- A plain-language description of each COVID-19 test that is offered by the provider;
- The billing code for each COVID-19 diagnostic test;
- The provider's cash price for each COVID-19 diagnostic test; and
- Any additional information necessary for the public to have certainty of the cash price that applies to each COVID-19 diagnostic test.

The additional information may include, for example, multiple cash prices for the same test and the distinguishing information for these prices in the case of a provider that offers the same test at a different cash price based on location or some other factor.

The information or a link to it must be displayed in a conspicuous location on the homepage of the provider's website, and must be displayed in a manner that is easily accessible without barriers. It must be made available free of charge, without requiring that a user establish an account or password, and without a user having to submit personal health information. The provider's home page must include all of the following terms: provider name; price; cost; test; COVID; and coronavirus. The presence of these keywords is intended to increase the likelihood that the public will locate the information using a search engine. **Comments are sought on whether providers should have flexibility to select between using "COVID" or "coronavirus" and between "cost" and "price" if the provider is linking to the information from its homepage.**

A provider of a COVID-19 diagnostic test that does not have its own website must make the required information public in writing within two business days upon request, and on a sign posted prominently in the location where the COVID-19 diagnostic test is offered, if that location is accessible to the public. Email correspondence to the requestor is considered an acceptable written format. These policies are expected to help ensure that the public has access to every provider's COVID-19 diagnostic test cash prices, including for those providers that do not perform the tests at publicly accessible locations. **Comments are sought on these issues, including the frequency by which providers may not have a website.**

More generally, CMS seeks comments on several additional issues:

- Addressing price gouging. Comments are sought on how to mitigate concerns that certain providers may use the posting of a cash price as an opportunity to price gouge. The comments should address whether the IFC definition of cash price, or an alternative definition would help mitigate concerns about price gouging by out-of-network providers. CMS also seeks comments on whether additional authorities and safeguards could be used to mitigate the concerns about price gouging for group health plans and issuers and for consumers receiving a COVID-19 diagnostic test.

- Additional safeguards. CMS asks whether the requirements in this IFC are sufficient to inform consumers of the cash price for a COVID-19 diagnostic test in advance of receiving one and what, if any, additional requirements or safeguards should be considered to avoid consumer confusion or prevent unintended consequences, such as balance billing. Comments are specifically sought on how providers should post cash prices so that they do not inadvertently deter consumers from seeking a test that would normally result in no out-of-pocket cost to the consumer.
- Impact. Comments are sought on whether and to what extent the IFC policies and alternatives for which comments are sought, such as expanding the definition of COVID-19 diagnostic test provider, may lead to:
    - Potential cost shifting from providers or participants, beneficiaries, and enrollees to group health plans or issuers that did not previously cover COVID-19 diagnostic testing without cost-sharing and as payment in full.
    - Potential for group health plans or issuers to negotiate rates that are lower than the cash price with out-of-network providers with whom they do not have established negotiated rates.
    - Price gouging or other anti-competitive behavior by providers as well as any potential negative impact on premiums in the future that have not already been accounted for in 2021 rates. CMS asks commenters to please provide empirical evidence, if any, including based on claims data during the PHE for COVID-19.
    - Potential savings to issuers and plans from insured consumers seeking out COVID-19 diagnostic testing from in-network providers, as opposed to the provider of their choice, as a result of these increased price transparency requirements;
    - Price sensitivity by consumers covered by group health plans or issuers in their choice of provider, and awareness of any potential cost-shifting to group health plans or issuers, or to consumers themselves through balance billing, as a result of these increased price transparency requirements.
    - Transparency benefits for the uninsured, who may already have an incentive to find the lowest price.
    - Group health plans or issuers taking on new consumer education or other potential costs, for example, costs associated with incentivizing consumers covered by group health plans or issuers to stay in network or seek care from lower cost providers.

3. Monitoring and Penalties for Non-compliance (§182.50, §182.60, §182.70, §182.80, §182.90)

If CMS concludes that a provider of a COVID-19 diagnostic test is noncompliant with one or more requirements of §182.40, it may take any of the following actions: (1) provide a written warning to the provider of specific violations; (2) request that the provider submit and comply with a corrective action plan; or (3) impose a civil money penalty on the provider if the provider fails to submit a corrective action plan or fails to comply with a corrective action plan approved by CMS.

Violations requiring a corrective action plan include failure to make public its cash price information and failure to make cash price information public in the form and manner required

under §182.40. CMS would request submission of a corrective action plan in a notice of violation providing a deadline for submission. The corrective action plan must specify the corrective actions or processes the provider will take to address the deficiencies identified by CMS and the timeframe by which the provider will complete the corrective actions. Other elements may be required. The corrective action plan is subject to CMS review and approval. CMS may monitor and evaluate a provider's compliance with the corrective actions specified in an approved corrective action plan.

CMS may impose a civil money penalty on a provider that it identifies as (1) noncompliant with the requirements of 182.40 and (2) that has failed to respond to CMS' rest to submit a corrective action plan or fails to comply with the requirements of an approved corrective action plan. CMS is required to provide written notice of the penalty via certified mail or other traceable form. The notice may include (1) CMS' determination as to which requirements the provider has violated, the provider's failure to respond to CMS' request for submission of a corrective action plan or failure to comply with the requirements of an approved corrective action plan; (2) the effective date for the violations; (3) the amount of the penalty as of the date of the notice; (4) a statement that the civil monetary penalty may continue to be imposed for ongoing violations; (5) instructions for payment; (6) a statement of the provider's right to a hearing; and (7) a statement that failure to request a hearing within 30 calendar days of issuance of the notice permits the imposition of the penalty and any subsequent penalties pursuant to continuing violations, without right of appeal. If there is an appeal and the penalty is upheld by a final and binding decision, CMS will issue a modified notice of imposition of a civil monetary penalty that conforms to the final decision.

CMS seeks comment on its approach for monitoring providers of COVID-19 diagnostic testing for compliance with the price transparency requirements and on specific elements. Specific comments are sought on relying predominantly on complaints to determine a provider's noncompliance, and on issuing warning letters and requesting corrective action plans. Comments are also sought on the length of time that should be specified in warning notices to allow correction of deficiencies before requesting submission of a corrective action plan, and on the length of time that should be given to providers to return a corrective action plan to CMS.

A civil monetary penalty may be imposed on a provider for a violation of each requirement, with a maximum daily dollar amount of $300. The maximum amount is adjusted annually using the multiplier determined by the Office of Management and Budget for this purpose.

Payment in full is required within 60 calendar days after the date of the notice of imposition of a civil monetary penalty from CMS, except that if a hearing is requested, the provider must pay the amount in full within 60 calendar days after the date of a final and binding decision, that upholds some or all of the civil monetary penalty. Collection activities set forth in 45 CFR part 30 will be followed by CMS if payment is not made in full by the applicable deadline.

A provider may appeal a penalty. CMS models the regulations regarding appeals in §182.80 on the appeals process set forth under the hospital price transparency regulations at 45 CFR 180.100

and 180.110.[9] In considering whether the penalty is reasonable, the Administrative Law Judge may only consider evidence of record relating to the provider's posting of its cash price information, if available; material the provider submitted to CMS timely; material used by CMS to monitor the provider's compliance If a provider does not request a hearing within 30 calendar days of the issuance of the notice of imposition of a civil monetary penalty, CMS may impose the civil monetary penalty indicated in such notice without right of appeal in accordance with this part. The provider has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with unless the provider can show good cause for failing to timely exercise its right to a hearing.

Comments are sought on the approach for imposing civil monetary penalties, specifically on the length of time allowed between requesting a corrective action plan and the imposition of a civil monetary penalty. In addition, comments are sought on the amount of the penalty to be imposed per day up to the statutory daily maximum.

4. Impact Analysis

In the Regulatory Impact Analysis section of the IFC, CMS states that it anticipates that price transparency has potential beneficial marketplace benefits generally and refers readers to the 2020 Hospital OPPS final rule for discussion of hospital price transparency provisions (84 FR 65524) and the Transparency in Coverage Proposed Rule (84 FR 65464). Price transparency in COVID-19 diagnostic testing is expected to help improve clarity for consumers and the plans and issuers that are required to cover the cost of performing a COVID-19 diagnostic test when there is no negotiated rate between the plan or issuer and the provider, as the posted prices are expected to provide a baseline against which negotiations can occur. In addition, posting of cash prices will assist individuals who are uninsured and price shopping for COVID-19 diagnostic tests.

CMS cites estimates from the literature of the savings associated with broader price transparency and extrapolates the median result to estimate savings from price transparency in COVID-19 diagnostic testing. The result is savings in consumer expenditures that range from $13 million to $254 million annually; the figures combine transfers from providers to insurers and patients with savings in societal resources. CMS notes that savings would be lower if the remainder of the COVID-19 PHE is less than one year.

Compliance with the price transparency requirements involves collecting, compiling, and posting the required information. CMS estimates the costs of compliance to be a one-time cost per provider of $72.62, totaling about $6 million across 83,309 CLIA-certified laboratories nationally (30 percent of all CLIA-certified laboratories).

[9] These regulations were finalized in November 2019 (85 FR 65524). They do not yet appear on the ecfr.gov website.

D. Medicare Hospital Inpatient Prospective Payment System (IPPS): New COVID – 19 Treatments Add-on Payment (NCTAP) for the PHE

CMS is using its authority under section 1886(d)(5)(I) of the Social Security Act to create a New Covid-19 Treatment Add-on Payment (NCTAP) under the IPPS for certain COVID-19 cases, effective November 2, 2020 and continuing through the duration of the COVID-19 PHE. As background for presenting this provision, CMS reviews several related policies:

- Under section 3710 of the CARES Act, the Medicare Severity Diagnosis Related Group (MS-DRG) weighting factor for a Medicare beneficiary with COVID under the IPPS is increased by 20 percent. This provision will be in effect for Medicare discharges during the COVID-19 PHE.
- The FDA has created the Coronavirus Treatment Acceleration Program[10] to move new treatments to patients as quickly as possible while finding out whether they are helpful or harmful. One aspect of the program is issuance of EUAs during the COVID-19 PHE. Five drug or biological products have received EUAs issued during the COVID-19 PHE; in two cases section "I. Criteria for Issuance of Authorization" of the letter of authorization states that based on the totality of the scientific evidence it is reasonable to believe that the product may be effective in treating COVID-19. These products are Veklury (remdesivir), which on October 22, 2020 was approved by FDA for treatment of COVID-19, and COVID-19 convalescent plasma. (The three other products receiving an EUA during the COVID-19 PHE treat a disease or condition caused or exacerbated by COVID-19.[11])
- A new technology add-on payment (NTAP) provides additional payment for high-cost cases involving new medical technologies. If the cost of a discharge involving a new technology exceed the full DRG payment (including adjustments for indirect medical education and disproportionate share hospitals but excluding outlier payments)), Medicare makes a new technology add-on payment equal to the lesser of: (1) 65 percent of the costs of the new technology; or (2) 65 percent of the amount by which the costs of the case exceed the full DRG payment. (See §§412.87 and 412.88.)
- Outlier payments are made under the IPPS for certain high cost cases. If costs exceed a fixed-loss cost threshold, the hospital receives 80 percent of the costs above the threshold (90 percent for burn cases). The fixed-loss cost threshold is the sum of a specified fixed-loss dollar amount reflecting local cost variation plus the DRG payment including the add-on payment under section 3710 of the CARES Act, payments for indirect medical education and disproportionate share hospitals and any new technology adjustment. Separate operating and capital outlier thresholds are calculated.

1. Eligibility for the NCTAP

Under the IFC, cases eligible for the NCTAP are those meeting the following three criteria:

- The case must include the use of a drug or biological product authorized to treat COVID-19 as indicated in section "I. Criteria for Issuance of Authorization" of the current letter

[10] https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap

[11] CMS identifies the three are REGIOCIT, used in Continuous Renal Replacement Therapy (CRRT); Fresenius Propoven 2 percent Emulsion, used to maintain sedation during mechanical ventilation in an ICU setting; and multiFiltrate PRO System and multiBic/multiPlus Solutions, also used in delivering CRRT.

of authorization for the drug or biological product, or the drug or biological product must be approved by the FDA for treating COVID-19. For purposes of Medicare's definition of drugs and biologicals,[12] CMS believes that it is appropriate to consider products authorized for emergency use for COVID-19, with letters of authorization. Further, CMS notes that the purpose of the NCTAP is to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments, and this criterion expeditiously provides assurance in that a treatment is new and is used to treat COVID-19 during the PHE. As noted above, only Veklury (remdesivir) and COVID-19 convalescent plasma currently meet this criterion. As drug and biological products become available that meet this criterion, cases that use those products would become eligible for the NCTAP if the remaining criteria are met.

- The case must also be eligible for the 20 percent increase in the weighting factor for the assigned MS-DRG that was established under section 3710 of the CARES Act for an individual diagnosed with COVID-19 discharged during the period of the PHE. CMS states that the primary purposes of this criterion are to help appropriately identify COVID-19 cases and ensure for program integrity reasons that there is a positive COVID-19 laboratory test documented in the patient's medical record. CMS says that it 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.
- 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. CMS says the purpose of this criterion is to ensure that the NCTAP is made only when needed. 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 notes that no Medicare requirements during the PHE are being waived by the creation of the NCTAP policy. All generally applicable statutory and regulatory requirements during the PHE for Medicare payment for a particular case must continue to be met, and that the NCTAP will only be available to the extent that the new COVID-19 treatment meets all Medicare coverage requirements under Medicare, including that the use of a drug or biological product is medically reasonable and necessary for that case.

2. Determination of the IPPS NCTAP Amount

The NCTAP amount for a case that meets the NCTAP eligibility criteria will equal 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 adjustment to the relative weight under section 3710 of the CARES Act. As with the new technology add-on payment and outlier payments, the costs of the case are determined by multiplying the covered charges by the operating cost-to-charge ratio. In addition, the NCTAP will not be included as

[12] Section 1861(t)(1) of the Act defines drugs and biologicals to include drugs or biologicals approved for inclusion in certain compendia (except for any drugs and biologicals unfavorably evaluated therein) or that are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of a hospital furnishing that drug or biological for use in that hospital.

part of the calculation of the operating outlier payments – CMS wants to avoid inadvertently reducing outlier payments that the hospital would otherwise have received with this policy.

In making this policy, CMS notes that the outlier policy already helps mitigate the financial disincentives for a hospital to provide new COVID-19 treatments. However, under that policy the costs must exceed an outlier threshold which for 2021 is about $30,000. CMS intends that the NCTAP should partially offset costs that are greater than the Medicare payment, but less than the outlier threshold. By only partially offsetting costs, CMS believes that the NCTAP policy will support the inherent average-based nature of the IPPS.

The NTAP payment calculation serves as a model for the NCTAP calculation. However, for the NCTAP calculation CMS does not make a comparison to the costs of the new treatment, noting the operational challenges and a desire to make the NCTAP expeditiously during the COVID-19 PHE.

CMS provides what it refers to as two simplified examples of the NCTAP.

- If the cost of a case using a new COVID-19 treatment exceeds the operating IPPS payment by $10,000 and the operating outlier threshold for the case is (for purposes of illustration) $30,000, the NCTAP would be $6,500 ($10,000 excess cost x 0.65). No outlier payments would be made because the excess cost of the case ($10,000) does not exceed the operating outlier threshold for the case ($30,000).
- If the cost of a case using a new COVID-19 treatment exceeds the operating IPPS payment by $100,000, the NCTAP would be equal to the maximum NCTAP amount of 65 percent of the operating outlier threshold for the case. In this illustrative example, if the applicable operating outlier threshold for the claim is $30,000, that amount is $19,500 (first $30,000 of the excess cost before the operating outlier threshold for the claim is reached x 0.65). In addition, in this case an outlier payment would be made, calculated the same way it is currently calculated in the absence of the $19,500 NCTAP, that is, $56,000 (($100,000 excess cost less the $30,000 outlier threshold for the case) * the 0.80 outlier marginal cost factor). The combined NCTAP and outlier payment would be $75,500 (the $19,500 enhanced payment + the $56,000 outlier payment).

CMS adds that hospitals should not seek additional payment for drugs and biologicals that are procured or provided to the hospital by a government entity at no cost to the hospital.

3. Procedure Codes

The procedure codes that will be used to identify cases using remdesivir and convalescent plasma are shown below. More information on the new procedure codes implemented into the International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) in response to the COVID-19 PHE is available on from CMS at https://www.cms.gov/files/document/icd-10-msdrgs-version-372-effective-august-01-2020.pdf. CMS will issue additional operational instructions on how eligible cases will be identified, including any new treatments that may become available.

XW033E5	Introduction of Remdesivir Anti-infective into Peripheral Vein, Percutaneous Approach, New Technology Group 5
XW13325	Transfusion of Convalescent Plasma (Nonautologous) into Peripheral Vein, Percutaneous Approach, New Technology Group 5
XW14325	(Transfusion of Convalescent Plasma (Nonautologous) into Central Vein, Percutaneous Approach, New Technology Group 5

E. Medicare Outpatient Prospective Payment System (OPPS): Separate Payment for New COVID–19 Treatments Policy for the PHE

The IFC creates an exception under the OPPS to provide for separate payment of certain new COVID-19 treatments during the PHE, should any become available for the outpatient setting. Currently there are no drugs or biological products with FDA approval or an EUA for treating patients with COVID-19 in the outpatient setting.

CMS anticipates that most new drugs and biological products authorized for treatment of COVID-19 in the outpatient setting would be paid separately under the OPPS because drugs and biologicals usually are not be packaged with other services. However, payment for COVID-19 drugs and biologicals would be packaged into payment for a Comprehensive APC (C-APC) service when billed on the same claim as that service. In particular, CMS cites the potential use of C-APC 8011, "Comprehensive Observation Services," for COVID-19 patients under observation in the outpatient setting while the provider determines if an inpatient admission is necessary.

The exception created in this IFC provides that any new COVID-19 treatment that meets two criteria will 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. The two criteria are for (1), 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, and (2) the EUA for the drug or biological 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.

CMS notes that at this time Veklury (remdesivir) and COVID-19 convalescent plasma meet the first criteria, but neither is authorized or approved for use in the outpatient setting and therefore, no product meets the second criterion.

The policy of separate payment for new COVID-19 treatment policy will be effective November 2, 2020 until the end of the COVID-19 PHE. CMS notes that separate payment will result in an additional beneficiary copayment of 20 percent of the cost of the new COVID-19 treatment, up to the amount of the Medicare inpatient deductible ($1,408 in 2020).

CMS notes that no Medicare requirements during the PHE are being waived by the creation of the C-APC exception. All generally applicable statutory and regulatory requirements for Medicare payment under the OPPS must continue to be met, and that the OPPS payment will

only be available to the extent that the new COVID-19 treatment meets all Medicare coverage requirements, including that the use of a drug or biological product is medically reasonable and necessary for the patient.

CMS believes that no adjustment to OPPS budget neutrality calculations is required for this policy. Use of the C-APC exception is expected to be infrequent, as a new COVID-19 treatment would only rarely appear on the same claim as a primary C-APC service. That is, current OPPS policy would generally provide for separate payment of new COVID-19 treatments used in the outpatient setting. As a result, any budgetary effect of this new exception is likely to be de minimis. Once new COVID-19 treatments are being provided in the outpatient setting, CMS will adjust the budget neutrality calculations in future rulemaking as needed based on actual claims experience.

F. Temporary Increase in Federal Medicaid Funding

1. Background

Under section 6008 of FFCRA, as amended, states can qualify to receive a temporary 6.2 percentage point increase in their federal Medicaid matching percentage through the last day of the calendar quarter in which the COVID-19 PHE ends. In order to qualify for the additional federal share of Medicaid payments, a state must meet the following four conditions:[13]

(1) The state must maintain eligibility standards, methodologies, or procedures that are no more restrictive than those in place as of January 1, 2020.
(2) The state may not charge premiums in excess of those in place as of January 1, 2020.
(3) The state must cover testing and treatment for COVID-19, including vaccines, specialized equipment, and therapies without cost sharing.
(4) The state must maintain coverage for a person enrolled in Medicaid on March 18, 2020 or who enrolls during the period starting March 18, 2020 through the last day of the month in which the PHE for COVID-19 ends. This applies whether the individual is enrolled under the state Medicaid plan or under a demonstration waiver. Exceptions include if the individual requests a voluntary termination of eligibility or the individual ceases to be a resident of the state. (section 6008(b)(3)).

CMS has heretofore interpreted section 6008(b)(3) to mean that a state must keep beneficiaries enrolled in Medicaid if they were enrolled on or after March 18, 2020 with the same amount, duration, and scope of benefits.[14] States could not drop optional benefits nor subject beneficiaries to any increase in cost sharing or liability for services including for institutional or other long-term services and supports.

This interpretation means that if a beneficiary's circumstances were to change, such that under traditional rules, they would become ineligible for benefits altogether, or eligible for a different eligibility group that covers more limited benefits, states may not disenroll those individuals nor

[13] The first three conditions extend through the end of the increased FMAP period. The fourth applies through the last day of the month in which the PHE for COVID-19 ends.
[14] See Families First Coronavirus Response Act – Increase FMAP FAQs, https://www.medicaid.gov/state-resource-center/downloads/covid-19-section-6008-faqs.pdf.

transition them to the new eligibility group. Exceptions to this provision were if a beneficiary requested to be disenrolled or was no longer a resident of the state or had died.

Further, states receiving enhanced matching funds could not implement new restrictions on coverage for those individuals – preventing states from dropping optional benefits, imposing restrictions or reductions in covered visits, or imposing new prior authorization requirements. Nor could states alter the benefits for individuals who no longer meet level-of-care requirements. The result of the interpretation is that no enrollee on the program as of March 18 or entering during the PHE may have their benefits or coverage reduced during the PHE.

CMS notes that states have raised concerns that this interpretation limits state flexibility to control program costs at a time when states are struggling with fiscal challenges related to the pandemic and the corresponding economic changes. Further, the only remaining cost control measure available to states is to reduce provider rates – raising concerns about provider solvency and the ability of states to maintain critical provider networks.

2. Alternate Interpretation

CMS describes a potential alternate interpretation of section 6008(b)(3) under which states would be required to maintain enrollment of the beneficiary but not to maintain the same level of coverage. Under this interpretation, a state could eliminate optional benefits or impose other programmatic changes that reduce the amount, duration, or scope of coverage. They would be required to transition a beneficiary who becomes ineligible for his current eligibility group to another group for which he is eligible even if the new group qualifies for more limited coverage. If the person did not qualify for another eligibility group, the state would need to maintain the individual's coverage as under the existing interpretation.

Under this alternate interpretation, a person could be transitioned to an eligibility groups for which the benefits are not considered minimum essential coverage (MEC).[15] Such groups include the optional eligibility group providing only family planning and related services and the optional coverage group providing only for tuberculosis- and tuberculosis-related services. Such individuals could lose access to some medically necessary services as well as access to testing and treatment services for COVID-19.

3. CMS adopts a blended approach

CMS weighs concerns that the present interpretation raises financial challenges for states and the alternate interpretation could leave individuals including those with chronic conditions at higher risk of losing coverage and potentially increasing their vulnerability to COVID-19. In the IFC, CMS adopts a blended approach that seeks to permit states to make some changes to ensure the states' and program' sustainability but includes protections for beneficiaries at risk of losing coverage. The blended approach described below becomes applicable on the date of display and extends through the end of the month in which the PHE ends.

[15] MEC is defined in section 5000A(f)(1) of the Internal Revenue Code and relates to coverage that is sufficient to meet the ACA shared responsibility requirement. In most cases, it is coverage that has a minimum actuarial value of 60% and covers 10 essential health benefits.

Under the approach adopted by CMS, states will be permitted to make programmatic changes to benefits and cost sharing and to transition beneficiaries between eligibility groups, but within certain limitations to prevent beneficiaries from losing access to comprehensive coverage through the end of the month in which the PHE for COVID-19 ends.

Under new 42 CFR part 433, Subpart G – Temporary FMAP Increase During the PHE for COVID-19, states are required to maintain a beneficiary's "valid enrollment" in an eligibility group that provides one of three tiers of coverage.

- For beneficiaries whose Medicaid coverage meets the definition of MEC as of or after March 18, 2020, the state must continue to provide Medicaid coverage that meets the definition of MEC. This requirement is deemed met for beneficiaries who become eligible for coverage under a Medicare Savings Program since Medicare coverage is considered to be MEC.
- For beneficiaries whose Medicaid coverage as of or after March 18, 2020 does not meet the definition of MEC but does include coverage for testing services and treatments for COVID-19, including vaccines, specialized equipment, and therapies, the state must continue to provide Medicaid coverage that includes such testing services and treatments.
- For all other beneficiaries, the state must continue to provide at least the same level of medical assistance that was provided as of, or after March 18, 2020.

If a state determines that a validly enrolled beneficiary is no longer eligible for Medicaid, including on a procedural basis, the state meets these requirements by continuing to provide the same Medicaid coverage that the beneficiary would have received absent the determination of ineligibility.

The existing exceptions continue to apply – for those who request disenrollment, those who cease to be a resident of the state, or those who die. In addition, under the new rules,

- A state may terminate an individual who is not "validly enrolled" as defined below. CMS notes that prior to terminating an enrollee who is not "validly enrolled" the state must complete a redetermination and provide the beneficiary with advance notice and an opportunity for fair hearing. "Validly enrolled" is defined to mean that the beneficiary was enrolled in Medicaid based on a determination of eligibility. A beneficiary is not validly enrolled if the agency determines the eligibility was erroneously granted at the most recent determination, redetermination, or renewal of eligibility (if such last redetermination or renewal was completed prior to March 18, 2020) because of agency error or fraud or abuse attributed to the beneficiary or the beneficiary's representative, which was material to the determination of eligibility. Individuals receiving medical assistance during a presumptive eligibility period (whose final determination has not been confirmed) are not considered validly enrolled beneficiaries for purposes of this section.
- A state will be considered in compliance with the rules if a beneficiary requests to be terminated from an eligibility group with a more generous level of coverage and to be enrolled in another eligibility group (that they qualify for) with a less generous level of coverage.
- If a beneficiary is identified via the Public Assistance Reporting Information System (which could indicate that he is enrolled in more than one state program) and doesn't

respond to requests for information to verify his residency, the state may consider the individual as no longer a resident of the state.

In addition to the definition of "validly enrolled", CMS includes in new Subpart G the following new definitions:

COVID-19 means Coronavirus Disease 2019.

Medicare Savings Program means the coverage of Medicare premiums and cost sharing furnished to individuals described in, and determined by the state to be eligible under, section 1902(a)(10)(E)(i), 1902(a)(10)(E)(iii), or 1902(a)(10)(E)(iv) of the Act.

Minimum essential coverage (MEC) has the meaning provided under section 5000A(f)(1) of the Internal Revenue Code and implementing regulations at 26 CFR 1.5000A-2 and includes minimum essential coverage determined by the Secretary under 26 CFR 1.5000A-2(f).

Public Health Emergency for COVID-19 has the same definition as provided in §400.200.

Temporary FMAP increase means the 6.2 percentage point increase in the State's federal medical assistance percentage (FMAP) that is authorized under section 6008(a) of the FFCRA through the end of the fiscal quarter in which the Public Health Emergency for COVID-19 ends.

4. Regulatory Impact

CMS does not quantitatively estimate the impact of providing states with additional flexibility to transition beneficiaries between eligibility groups, but discusses the impact qualitatively. It expects that some states will implement cost saving measures under this flexibility and will experience reduced financial burden as a result. It does not, however, know how many states will enact changes nor exactly what changes states will choose to make since the flexibilities permit a variety of state actions.

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

Through this IFC, CMS implements four changes to the CJR model to minimize disruption of model operations for participants (CJR hospitals) and for the agency while the COVID-19 PHE continues without a specified endpoint. CMS notes being unable to confidently estimate cost or savings from these changes internally within CMMI (Centers for Medicare and Medicaid Innovation) and further notes that the CMS Office of the Actuary was unable to create projections regarding Medicare spending under the CJR model in 2021. CMS attributes the barriers to impact analysis to multiple factors, including the month-to-month variation in CJR operative volumes thus far during 2020 (see Table 1 below), and methodology changes that have occurred but for which claims experience is still accumulating.

1. Extending Performance Year 5

CJR was originally designed to end its fifth and final performance year (PY 5) on December 31, 2020.[16] CMS has proposed but not yet finalized a 3-year extension of the model and states that their consideration of the comments received is ongoing.[17] Subsequently, in the April 6, 2020 IFC dealing with the COVID-19 PHE (85 FR 19263), CMS extended PY 5 through March 31, 2021. CMS now further extends PY 5 to run through September 30, 2021, creating a 21-month total PY 5 performance period duration, to enhance operational stability for participants while the PHE continues and lower extremity joint replacement operative volumes recover. Further extension of PY5 related to the COVID-19 PHE was supported by April 2020 IFC commenters.

CMS notes that extending CJR PY5 through September 2021 would conflict with the timeline for the proposed PYs 6-8, if finalized. **CMS requests comment on the duration of PY 6 :**

- **Should PYs 6-8 each remain 12-month performance years and each begin with episodes ending on or after October 1 each year (PYs 6-8 total duration October 1, 2021 through September 30, 2024)?**
- **Alternatively, should PY 6 instead run for 15 months, October 1, 2021 through December 31, 2022, followed by PYs 7 and 8 that would each run for 12 months beginning with episodes ending on or after January 1, 2023 and January 1, 2024, respectively (PYs 6-8 total duration October 1, 2021 through December 31, 2024)?**

2. Revising Performance Year 5 Reconciliation

The CJR model reconciliation process determines if a participant will receive a net payment reconciliation amount (NPRA) or will owe a recoupment payment to CMS. Currently, the following steps occur after each PY: 1) in late February. after a 2-month claims runout period, the initial (first) reconciliation begins; 2) in late February of the following year, after a 14-month claims runout period, the final (subsequent) reconciliation begins; 3) the initial and final reconciliation results are netted into a single NPRA or recoupment amount; and 4) the single, net reconciliation result for the applicable PY is issued to participants in June.

Extending PY 5 to 21 months, as described above, also would create a 21-month interval between the final reconciliation for PY 4 (June 2020) and the initial reconciliation for PY 5 (February 2022). CMS states their belief that this delayed PY 5 reconciliation would confound a participant hospital's self-assessments of quality and costs for joint replacement; affect the hospital's gainsharing relationships; and violate the terms of the CJR model's design. CMS, therefore, will split the prolonged PY 5 into two segments. Performance year subset 5.1 includes 12 months (CY 2020) and PY subset 5.2 covers 9 months (January through September 2021). Reconciliation for PY subset 5.1 will thereby mimic what would have occurred for the entirety of PY 5 absent changes made for the PHE. CMS will conduct separate initial and final

[16] Each CJR performance year (PY) encompasses a full calendar year except for PY 1, which ran for 9 months from the model's inception April 1, 2016 through December 31, 2016.
[17] The proposed rule adding PYs 6-8 (CMS-5529-P) was published February 24, 2020 (85 FR 10516 through 10550). Each PY would run for a full calendar year; PY6 was proposed to begin January 1, 2021. The rule also includes other changes, such as incorporating outpatient lower extremity joint replacement episodes into the model.

reconciliations for each PY subset, as depicted in Table 2 from the rule (reproduced below). CMS will also calculate separate Composite Quality Scores for PY subsets 5.1 and 5.2.[18] CMS notes that portions of the quality data collection periods of the PY subsets 5.1 and 5.2 will overlap with the effective dates of the waiver that created COVID-19 PHE-related exemptions under hospital quality reporting programs;[19] CJR quality data from exempted periods will be excluded from CJR reconciliation calculations.

CMS discusses how the split PY 5 reconciliation process will differ from that for prior PYs. First, CMS will pull claims for the PY subset 5.2 initial reconciliation in December 2021 instead of late February 2022. Second, calculations for the PY subset 5.2 initial reconciliation will begin at 5 months after the PY subset ends (late February 2022) rather than the usual 2 months. Third, calculations for the PY subset 5.2 final reconciliation will begin at 17 months after PY subset 5.2 ends (late February 2023) rather than the usual 14 months. CMS states that these changes will retain a 2-month claims runout period throughout the model, maintain alignment of the initial reconciliation for each PY with the final reconciliation of the preceding PY, and allow CMS to acquire all of the input files needed for their calculations.[20]

Table 2: Timelines for Performance Years 4 and 5

Performance Year (PY)	Performance Period	Initial (First) Reconciliation Calculation Start	Subsequent (Final) Reconciliation Calculation Start	Reconciliation Amount (+/-)
4	1/1/2019 to 12/31/2019	2 months after 12/31/19: late February 2020	14 months after 12/31/19: late February 2021	Net PY3 and PY4 reconciliation amounts
5 (two periods)	1/1/2020 to 9/30/2021			
Subset 5.1	1/1/2020 to 12/31/2020*	2 months after 12/31/20: late February 2021	14 months after 12/31/20: late February 2022	Net PY4 and PY5.1 reconciliation amounts (June 2021)
Subset 5.2	1/1/2021 to 9/30/2021	5 months after 9/30/21: late February 2022	17 months after 9/30/21: late February 2023	Net PY5.1 and PY5.2 reconciliation amounts

* Shown in the IFC preamble as 12/31/2021; changed by HPA to be consistent with the regulatory text at §510.2.

3. Adding DRGs for Inclusion in the CJR Model

With this IFC, CMS retroactively adds 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* to the CJR model episode definition as of October 1, 2020. These two new MS-DRGs were finalized during FY 2021 IPPS rulemaking and were supported by commenters. Admissions under the new MS-DRGs were

[18] CMS will separately calculate quality improvement points and quality performance points for subsets 5.1 and 5.2.
[19] The waiver memo is available at https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf
[20] In addition to cost and quality data, these files include reconciliation results from ACOs (e.g., Medicare Shared Savings Program) that are needed for the CJR model overlap calculation.

formerly captured by CMS using MS-DRGs 469 and 470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC and without MCC, respectively), then subdivided within each MS-DRG by presence of hip fracture using a CMS-maintained list of hip fracture ICD-10-CM diagnostic codes.

CMS justifies the retroactive change by stating that failure to add MS-DRGs 521 and 522 to the CJR model promptly would eliminate 20-25% of model episodes during the model test period and thereby would be highly disruptive to participants and to the agency. CMS further states that the addition will be seamless for hospitals. Assignment to the new MS-DRGs is automatic through the Medicare IPPS grouper using hospital claims as currently submitted, and upcoming data feeds to model participants will include the new MS-DRGs. Adding the new MS-DRGs also achieves some administrative simplification for CMS.

Relatedly, CMS incorporates the new MS-DRGs and their respective weights into the separately determined quality-adjusted target prices for episodes with and without hip fractures for the remainder of PY 5 (both subsets). CMS describes accomplishing this for episodes beginning October 1, 2020 by: 1) applying the episode prices for MS-DRGs 469 and 470 to episodes falling under MS-DRGs 521 and 522, respectively; and 2) applying to those prices the usual CJR update factors, designed to capture fiscal and calendar year Medicare payment system updates (e.g., MS-DRG weight changes). CMS projects minimal financial impact on the CJR model and notes that hospitals were already aware of their quality-adjusted target prices for episodes falling under MS-DRGs 469 and 470 and having hip fracture diagnoses.

4. Modifying the Extreme and Uncontrollable Circumstances Policy for the COVID-19 PHE

CMS established a CJR model policy to mitigate potential adverse impacts of extreme and uncontrollable circumstances in June 2018 (83 FR 26604). The policy limits financial impacts by capping an affected participant's actual episode payments during the emergency period at the target prices determined for those episodes under §510.300, eliminating downside risk. In the IFC published April 6, 2020 in response to the COVID-19 PHE (85 FR 19264), the applicability of the policy solely to natural disasters was expanded to include the COVID-19 PHE, and all CJR participants were found eligible for the policy's adjustments. Specifically, for all episodes triggered by admissions occurring on or within 30 days before the PHE's start date or that occur through the termination of the emergency period, actual episode payments are capped at the target price. CMS adopted the revised policy based on their projections of abrupt, large, and sustained declines in joint replacement operative volumes, procedures that are largely elective, except when associated with hip fractures. The revised policy was supported by commenters.

CMS subsequently has analyzed CJR operative volume data, shown below in Table 1 from the rule. After the expected early and significant decline, joint replacement procedure performance has rebounded substantially above levels and more quickly than anticipated by CMS, albeit not yet to pre-COVID-19 PHE levels. CMS notes that while the PHE declaration has been renewed several times, most recently on October 23, federal guidance to avoid elective operations has expired. CMS emphasizes that the higher-than-expected CJR operative volumes in combination with an uncertain end date for the PHE could preclude any savings to Medicare being generated by the model over its currently scheduled test period (through September 30, 2021).

Table 1: CJR Episode Volume Comparison

	February	March	April	May	June	July	August
2019	6214	6174	6515	6019	5836	6060	5838
2020	5245	3374	876	2242	4036	3838	3090

CMS states their belief that broad application of the CJR policy for extreme and uncontrollable circumstances is no longer necessary and modifies the policy in two ways:

- By specifying an end date to the COVID-19 CJR price adjustment --
  - Episode payments are capped at the quality-adjusted target prices (§510.300) for all episodes with trigger admissions occurring on or within 30 days before the PHE's start date or that occur on or before March 31, 2021 or the last day of the emergency period, whichever is earlier; and
- By limiting subsequent applicability of the policy --
  - After March 31, 2021 or the last day of the emergency period, whichever is earlier, episode payments are capped at the quality-adjusted target prices (§510.300) for all episodes that include a claim with a COVID-19 diagnosis code.[21]

CMS states these changes are consistent with policies for other CMMI models.

III. Provisions of the Interim Final Rule – Departments of Treasury, Labor and Health and Human Services

The CARES Act requires group health plans and health insurance issuers offering group and individual health insurance coverage to cover "qualifying coronavirus preventive services" without cost sharing. In the IFC, the three Departments that oversee health insurance -- Treasury, Labor, and Health and Human Services -- make several modifications to existing rules to incorporate the CARES Act requirements. In addition, certain clarifications around coverage of qualifying coronavirus preventive services are described.

1. Background

Under existing rules, group health plans and health insurance issuers offering group and individual health insurance coverage must cover the following preventive health benefits without copayments:

- Evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the USPSTF with respect to the individual involved.
- Immunizations that have in effect a recommendation from ACIP with respect to the individual involved.
- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).

[21] The ICD-10-CM diagnostic codes are defined as B97.29; U07.1; or any other ICD-10-CM diagnosis code that is recommended by the Centers for Disease Control and Prevention for the coding of a confirmed case of COVID-19.

- With respect to women, preventive care and screenings provided for in comprehensive guidelines supported by HRSA subject to certain exemptions and accommodations.

Those preventive benefits must be covered beginning with the plan year or policy year that starts on or after the date that is one year after the date of the recommendation or guideline. If a recommended preventive service is billed separately from an office visit, cost-sharing may be imposed on the office visit. Plans and issuers are not required to provide such benefits via out-of-network providers unless they do not have an in-network provider who can provide the service. The three Departments impose largely identical rules implementing those requirements at 45 CFR Part 147 (Department of Health and Human Services) with respect to individual and group insurance, 29 CFR Part 2590 (Department of Labor) with respect to employment based benefits, and 26 CFR Part 54 (Department of the Treasury) with respect to the application of taxes and penalties to health issuers or plans not in compliance.

2. Modifications to Incorporate CARES Act

To incorporate the CARES Act coronavirus preventive services requirement as well as to take the urgency of the existing PHE into account, the Departments make the following modifications and clarifications describing the requirements for health plans to cover preventive coronavirus-related health care services. The amendments in all three of the above sets of regulations are identical.

- Definition of "Qualifying Coronavirus Preventive Services." The Departments incorporate into existing preventive coverage regulations, a definition of qualifying coronavirus preventive services consistent with the definition in section 3203 of the CARES Act. It is defined as an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID-19) and that is, with respect to the individual involved— (A) An evidence-based item or service that has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force; or (B) An immunization that has in effect a recommendation from the ACIP of the CDC (regardless of whether the immunization is recommended for routine use). For this purpose, a recommendation from the ACIP is considered in effect after it has been adopted by the Director of the CDC.
- Coverage of Items and Services Integral to Coronavirus Preventive Services. The Departments clarify that plans must cover without cost sharing items and services that are integral to the furnishing of the recommended preventive service, regardless of whether the item or service is billed separately. They provide several examples including where a specimen must be collected to perform the recommended preventive service. Another example is coverage for an immunization and its administration fee. Both must be covered regardless of how administration is billed and whether the immunization requires the administration of multiple doses. They further clarify that if the immunization is not billed separately from an office visit and the primary purpose of the visit is the delivery of the COVID-19 vaccine, the plan or issuer cannot impose cost-sharing for the office visit.
- Rapid Coverage of Preventive Services for Coronavirus. Under existing rules, group health plans and health insurance issuers offering group and individual health insurance coverage must cover new recommendations beginning with the plan year or policy year

that starts on or after one year after the date of the recommendation or guideline. Because of the urgency of existing PHE, however, the CARES Act requires coverage of COVID-19 immunizations within 15 business days after the immunization has been recommended by ACIP and adopted by the CDC, regardless of whether it appears on the immunization schedules of the CDC for future use. The Departments adopt this rapid timeline with respect to coverage of qualifying preventive services for coronavirus.

- Out-of-Network Coverage. Under the existing preventive coverage requirements, plans and issuers need only cover without cost sharing the recommended preventive services provided by an out-of-network provider when they do not have an in-network provider who can provide the service. Because of the urgency of the PHE, the Departments require that plans and issuers must cover without cost sharing a qualifying coronavirus preventive service whether or not it is delivered by an in-network or out-of-network provider. This requirement is based on the concern that enrollees may not be able to locate in-network providers consistently or rapidly during the emergency period.
- Meaningful Payment for Out-of-Network Coverage. In addition, to ensure that such out-of-network coverage is meaningful, the Departments provide that with respect to a qualifying coronavirus preventive service provided by an out-of-network provider, the plan or issuer must reimburse the provider an amount that is reasonable, as determined in comparison to prevailing market rates for such service. The Departments provide, as an example of a reasonable amount of payment, the amount that would be paid under Medicare for the item or service.
- Sunset Date. The Departments provide that the amendments to implement CARES Act coverage of qualifying coronavirus preventive services sunset on the date that the PHE for COVID-19 expires.

3. Diagnostic Testing for COVID-19

The Departments are encouraging issuers of health plans to consider market-driven approaches to address challenges surrounding COVID-19 testing. For example, issuers could use payment arrangements to incentivize providers to reduce the amount of time it takes for providing results for diagnostic testing. Such pay-for-performance arrangements should be accompanied by safeguards to ensure that payment arrangements do not prioritize speed over accuracy, increase unintended negative consequences or reduce compliance with balance billing restrictions.

4. Regulatory Impact

The Departments do not quantitatively estimate the impact of required coverage of the costs of qualifying coronavirus preventive services without cost sharing but describe the potential effects qualitatively.

Plans and issuers are expected to incur the costs of the services as well as administrative costs of providing coverage within 15 business days. Those costs could impact premiums. The magnitude of the premium impact will depend on the cost of the vaccines, the vaccination rate and the number of people using in- versus out-of-network providers. The Departments seek comment on the potential costs and burdens to plans of such coverage and encourage plans and issuers to educate enrollees about the availability of services from in-network providers.

IV. Provisions of the Interim Final Rule Regarding State Innovation Waivers – Department of the Treasury and Health and Human Services

1. Background

States are permitted to apply for State Innovation Waivers under section 1332 of the ACA (also sometimes referred to as "section 1332 waivers" or "State Relief and Empowerment Waivers.") The waivers permit states to pursue innovative strategies for implementing health insurance and coverage reforms so long as such reforms meet certain financial and coverage guardrails.

Under existing law and rules, states applying for such waivers are required to provide for a state and federal public notice and comment period to ensure a meaningful level of public input. State comment periods may be no less than 30 days. In addition, after a waiver is in effect, states must provide for continued public input. The Departments describe the existing components of the state and federal public notice requirements.

2. Permitted Modifications to Public Notice Procedures

In the IFC, the Departments set forth a process for states to request modifications to the public notice procedures during the PHE, allow for the Secretaries to modify some of those procedures to expedite a decision on a proposed waiver request, and to limit the need for in-person gatherings.

The modifications are effective immediately and remain in place for the duration of the PHE for COVID-19.

Specifically, the Departments add identical provisions in new 31 CFR 33.1118 and 45 CFR 155.1318 to provide that the Secretaries may modify the state and federal public notice requirements to expedite a decision on a proposed waiver request during the PHE when a delay would undermine or compromise the purpose of the proposed waiver request and be contrary to the interests of the consumer.

It would permit the Secretaries of HHS and Treasury to modify the federal and/or state public notice procedures, in part, if the state:

- Requests a modification in the form and manner specified by the Secretaries.
- Acted in good faith, and in a diligent, timely, and prudent manner in the preparation of the request for the modification for the waiver, and the waiver application request.
- Details in its request for a modification the reasons and justification for the request, describes how the state meets the modification criteria, and describes the alternative public notice procedures it proposes to implement.
- Implements the alternative public notice procedures at the state level if the state's modification request is approved.

The Departments provide the following examples of modifications that may be permitted under this authority: A state could waive the requirement that it must hold more than one public hearing; the requirement to notify and hold public hearings before submitting an application; the requirement to provide for public notice and comment after the application is completed; or to modify the requirement that the state comment period is no less than 30 days. Virtual hearings could be requested as a substitute for in-person hearings.

The Secretaries remind states that any public participation process must comply with applicable federal civil rights laws, take reasonable steps to provide access to individuals with limited English proficiency, and effectively communicate with individuals with disabilities. They will publish on the CMS website any modifications granted. In addition, states must publish any modification requests and determinations on their websites within 15 calendar days of receipt of the determination as well as any revised timeline for public comment.

New provisions are also added to sections 33.120 and 155.1320(c) – requiring states to provide public notice for continued public input after a waiver has gone into effect. The amendments give the Secretaries the ability to modify post award public notice procedures when states make a request in the form and manner specified by the Secretaries, is acting in good faith, and details in its request how it will meet modified criteria that provide meaningful public hearing.

The Secretaries will issue modification determinations within 15 calendar days after a request is received.

3. Regulatory Impact

The Departments estimate that 15 states may seek modifications to the public notice requirements and in doing so altogether will incur a total cost of $1,775 for the time and effort to make the modification request and $319 for the cost of posting the approvals. The regulatory impact of the modifications is not estimated quantitatively but are described qualitatively. They note that to the extent that states receive approval for modifications, waivers will be approved more quickly but consumers may receive less notice. State comment periods may be shorter or conducted concurrently with the federal comment periods. They seek feedback on any potential costs and burdens that may be incurred by states as a result of the flexibilities offered in the IFC.

V. Waivers of Proposed Rulemaking

Under the Administrative Procedure Act (APA), CMS normally publishes a notice of proposed rulemaking in the Federal Register and invites public comment on the proposed rule before the provisions of the rule take effect. However the APA authorizes the agency to waive these procedures if it finds good cause that notice and comment rulemaking procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of finding and its reasons in the rule issued.

Further, the APA ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the *Federal Register*. This 30-day delay in effective date can be waived, however, if the agency finds good cause to support an earlier effective date, and such changes could be applied retroactively to items and services furnished before the effective date of the change if the failure to apply the changes retroactively would be contrary to the public interest.

Finally, the Congressional Review Act (CRA) requires a delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines.

The Departments find good cause to waive notice and comment rulemaking and the effective date delays under the APA and the CRA for this IFC. They argue that in light of the COVID-19

pandemic, it is critically important that the policies in this IFC be implemented as quickly as possible. The policies are intended to be in force during the COVID-19 PHE which is ongoing. Justifications offered in discussing these waivers include the following:

- Providing states with greater flexibility in order to receive the temporary increase FMAP is immediately necessary to ensure that states can determine eligibility and provide care and services during the PHE in a manner that is consistent with simplicity of administration and the best interests of beneficiaries.
- Following the normal timeframes and requirements could result in State Innovation Waiver approvals taking effect after issuers have already made their decisions regarding issuer participation in the individual market and after rates for the upcoming plan year have been submitted. The flexibility to modify certain public notice procedures and participation requirements will increase flexibility and reduce burden for states seeking to use section 1332 waivers as a means of innovation for providing coverage, lowering premiums, and improving their health care markets during the PHE for COVID-19.
- Amendments requiring that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide coverage without cost sharing for qualifying coronavirus preventive services are made under authority provided in 9833 of the IRC, section 734 of ERISA, and section 2792 of the PHS Act. These sections authorize the Departments to promulgate any interim final rules determined appropriate to carry out applicable statutes.
- Several COVID-19 vaccines are in late-stage development. As underscored by the timeline for coverage Congress established in section 3203 of the CARES Act, the need to provide coverage of qualifying coronavirus preventive services is urgent. The provisions of this IFC are immediately necessary to ensure group health plan and group and individual health insurance coverage of these items and services is prompt and broad, to ensure timely access to combat the pandemic.
- The requirements pertaining to Medicare cost plans under section 1876 are immediately necessary to ensure that cost plan enrollees, like other Medicare beneficiaries, are provided access to the COVID-19 vaccine and its administration without cost sharing. This immediate action will ensure that cost is not a barrier for beneficiaries to get the vaccine, particularly during the public health emergency when ensuring access is paramount importance.
- Requirements that providers of diagnostic tests for COVID-19 make public their cash prices for COVID-19 diagnostic tests are applicable during the PHE for COVID-19. It is, therefore, critically important to implement these policies as quickly as possible to ensure plans, issuers, and consumers know in advance the price for a diagnostic test for COVID-19 during the PHE for COVID-19. It would be impracticable and contrary to the public interest to undertake normal notice and comment rulemaking procedures and to delay the effective date of the new requirements being adopted at 45 CFR part 182.
- Using the to increase IPPS payment amounts for sufficiently costly cases will mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments during the PHE and will potentially improve and speed access to these treatments for Medicare patients. Establishment of the NCTAP also provides greater transparency and predictability to the public, including innovators that are developing new COVID-19 treatments, as to how Medicare payments for cases involving these treatments will be determined when those treatments become available.

- The delay necessary for notice and comment rulemaking to address the issue of payment under OPPS for drugs and biologicals that may become available and approved or authorized for the treatment of COVID-19 in the outpatient setting is both contrary to the public interest and impracticable because of the urgency in ensuring there are not financial disincentives for hospitals to provide COVID-19 treatments to beneficiaries.
- Extending the CJR model through an additional six months of PY 5, until September 30, 2021, while dividing the prolonged PY5 thus created into two subsets for reconciliation purposes, provides participant hospitals with greater certainty in model operations during the remainder of the PHE. Further, immediate addition of updated MS-DRGs to the definition of model episodes prevents loss from the model of procedures done for treatment of hip fractures; those cases have been intentionally included in the CJR model design from its inception. Taken together, these changes are immediately necessary to sustain the CJR model through the PHE by capturing nearly all inpatient major lower extremity joint replacements without interruption while reducing operational and financial uncertainty for CJR hospital participants.

VI. Regulatory Impact Analysis

The Departments have determined that this IFC will likely have an economic impact of $100 million or more in at least one year, and thus meets the definition of "economically significant" under Executive Order 12866 and a major rule under the Congressional Review Act. Notable findings from the regulatory impact analysis are discussed with respect to individual provisions in sections II, III and IV of this summary.