Wynne Health Group

Memorandum

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CMS Issues Fourth COVID-19 Interim Final Rule; Includes Vaccine and Diagnostic Coverage and Payment Policies, Among other Changes

On October 28, 2020, the Centers for Medicare & Medicaid Services (CMS) **released its fourth COVID-19 interim final rule (IFC), which includes several provisions to prepare for coverage of forthcoming vaccines and treatments for the disease** (press release; fact sheet).

Briefly, the new rule outlines policy changes in the following key areas:

- **COVID-19 Vaccines:** The rule implements coverage policies for vaccines and their administration for Medicare, Medicaid, and CHIP beneficiaries.
- **COVID-19 Treatments:** The IFC also implements Medicare payment policies for authorized COVID-19 treatments in the inpatient and outpatient settings.
- **Price Transparency:** CMS is requiring providers to publicly display the cash price for COVID-19 diagnostic tests.
- **Additional Provisions:** The IFC contains a number of other related changes, including those pertaining to –

    - Coverage of COVID-19 preventive services;
    - Extension of the CMS Comprehensive Joint Replacement model;
    - Revisions to Section 1332 waiver policy; and
    - Changes to rules around states receiving increases in their federal medical assistance percentage (FMAP) during the COVID-19 public health emergency (PHE).

Details on the rule's provisions follow.

- **Medicare Coverage of COVID-19 Vaccines** – Beginning on p. 13, CMS includes provisions to begin implementing section 3713 of the CARES Act, which authorized Medicare Part B coverage and payment of COVID-19 vaccines and their administration. CMS discusses the history of Medicare coverage of vaccines and notes that, while CMS has never covered vaccines authorized under an Emergency Use Authorization (EUA), the agency believes it appropriate to extend coverage to COVID-19 vaccines that may be approved via an EUA given the high-risk nature of the Medicare population. CMS adds that doing so is also consistent with Congress' general intent to provide for rapid coverage of COVID-19 vaccines.

    As for billing and coding, CMS states first that the CARES Act allows Medicare to cover the COVID-19 vaccine in the same way as it does the flu and pneumococcal vaccines. As such, Medicare will reimburse a COVID-19 at 95 percent of the average wholesale price.

    CMS further adds that it expects to establish a unique administration code for each COVID-19

vaccine that receives approval. Specifically, the agency says it will announce an interim coding and payment rate for a vaccine's administration once it receives licensure from the Food and Drug Administration (FDA). It will then address coding and payment rates for administration of the COVID-19 vaccine products through future notice-and-comment rulemaking.

Last, the agency notes it believes that the COVID-19 vaccines will be administered as one or two parenteral doses and will use the Part B influenza vaccination approach that permits certain providers and mass immunization to bill for the vaccine product. Therefore, CMS will accommodate a two dose initial COVID-19 vaccination schedule at this time.

- **Medicare Advantage and Cost Plans:** CMS confirms that all Medicare Advantage (MA) and cost plan organizations must cover a COVID-19 vaccine and its administration in line with Part B coverage under Original Medicare. MA plans and cost plans must cover the new benefit without cost sharing.

  CMS adds that, if coverage of a COVID-19 vaccine results in significant costs during the 2020 and 2021 contract years, coverage of the vaccines will be provided through Medicare fee-for-service (FFS) until the capitation payments take the new significant costs into account.

- **COVID-19 Vaccine Coverage for Medicaid, CHIP, and BHP Beneficiaries** – Beginning on p. 27, CMS explains that in order to continue to receive the 6.2% FMAP increase set up under FFCRA, states will be required to compensate Medicaid providers with a vaccine administration fee or reimbursement for a provider visit during which a vaccine dose is administered, even if the vaccine dose is furnished by the provider at no cost. For Medicaid programs with limited benefit offerings through demonstration programs or other arrangements, Medicaid programs would not be required to cover COVID testing and treatment without cost-sharing. Instead, HRSA's COVID-19 Claims Reimbursement program would cover vaccine and vaccine reimbursement costs for these individuals.

  On p. 29, the IFC outlines coverage requirements for after the enhanced FMAP ends. Specifically, states will continue to be required to cover COVID-19 vaccines recommended by the ACIP, including vaccine administration, for:

  - All Medicaid-enrolled children under 21 who qualify for EPSDT;
  - Medicaid-enrolled or uninsured, or Indian children who are given the vaccine by an FQHC, rural health clinic, under the Vaccines for Children (VFC) program, if CDC determines that the COVID-19 vaccine will be included;
  - Populations covered under Alternative Benefit Plans, including Medicaid adult expansion populations;

  Continuing to cover a COVID-19 vaccine and its administration for other groups who are eligible for the full state plan benefits such as parent/caretaker relatives, persons age 65 or older disabled individuals, and pregnant women will be up to states. States would have to proactively choose to

cover the vaccine and its administration for these individuals and would have to cover all groups if they choose to cover one group. In the case of 1115 demonstrations, the state may opt to amend their waiver. The exception to this is pregnant women: states can cover a vaccine and its administration as a pregnancy-related service while not providing the same coverage for other groups. States may apply cost-sharing once FFCRA no longer applies unless groups are exempt from cost-sharing (such as pregnant women, most children, etc.).

The IFC also outlines requirements for vaccine coverage for the Children's Health Insurance Program (CHIP), Basic Health Plans, Alternative Benefit Programs within Medicaid (ABPs) and others. It underscores that CMS intends for the IFC only to describe requirements as outlined under current policy and existing law, such as the FFCRA and the CARES Act, and not to make changes to that policy. FFCRA coverage requirements do not apply to the Children's Health Insurance Program (CHIP). CHIP must cover ACIP-recommended vaccines and their administration without cost-sharing for children under age 19. Coverage for uninsured pregnant women in CHIP is optional, although currently all states that cover pregnant women under CHIP do opt to cover vaccines. Basic Health Program (BHP) plans (which only exist in MN and NY) and Medicaid ABPs must provide coverage for and must not impose any cost-sharing for "qualifying coronavirus preventive services," including a COVID vaccine, regardless of whether the vaccine is delivered by an in-network or out-of-network provider during the COVID-19 public health emergency.

- **Price Transparency for COVID-19 Diagnostic Tests** – Beginning on p. 33, CMS issues changes that will require providers of diagnostic tests for COVID-19 to make the cash price for such tests public on the internet. Specifically, CMS finalizes the following:

    - **Types of tests:** These requirements apply to all in vitro tests, including molecular, antigen, and serological tests.

    - **Diagnostic Providers:** CMS defines a provider of a diagnostic test for COVID-19 as any facility that performs one ore more COVID-19 diagnostic tests.

    - **Cash Price:** CMS defines cash price as the charge that applies to an individual who pays in cash (or cash equivalent) for a COVID-19 diagnostic test. CMS states it expects the cash price will generally be similar to or lower than rates negotiated with in-network plans and insurers. Furthermore, the agency says that if a provider has not established a cash price that is lower than its gross charge or retail rate, the provider must make public the undiscounted gross or retail rate found in its master price list.

    - **Online Display of Cash Price:** CMS is requiring that each provider of a diagnostic test for COVID-19 to make public the cash price for such a test on the provider's public website. CMS states the information must appear in a conspicuous location on a searchable homepage on the provider's website. If a provider does not have a website, CMS says, then the provider must provide the cash price information in writing within two business days upon request, and by posting signage prominently at the location where the provider offers

the COVID-19 diagnostic test. CMS says that all provided information must be in plain language.

- **Penalties:** For providers that do not comply with these requirements, CMS states it is authorized to impose a civil monetary penalty (CMP) of up to $300 per day of non-compliance. To monitor for non-compliance, CMS says it anticipates relying heavily on complaints made to CMS by the public.

- **Temporary Increase in Federal Medicaid Funding** – The Families First Coronavirus Act (FFCRA) instituted certain requirements that states must meet in order to receive the 6.2% FMAP increase including (a) maintaining eligibility standards, methodologies or procedures, (b) not charging premiums higher than what was in place at the beginning of 2020, and (c) covering COVID testing and treatment without cost-sharing, including vaccines, specialized, equipment and therapies.

  Since implementing these FMAP changes, CMS has received feedback from states asking for greater flexibility. States are concerned that current interpretation which prohibits states from changing the benefit packages that individuals were enrolled in as of March 18, 2020 is untenable in light of the budget constraints that have arisen in the pandemic. Current prohibitions on states creates barriers to their ability to main manage their programs effectively and still qualify for the enhanced FMAP as they cannot transition enrollees from one eligibility category to another. States are also concerned that this will create a large backlog of redeterminations after the PHE ends. They assert that the only option open to states is to cut provider rates which would weaken already fragile provider networks.

  Given this, CMS has reconsidered its interpretation of the FFCRA and is proposing a "blended approach" that it asserts meets states' needs while also protecting providers and beneficiaries. Under the new guidance, states would still be eligible for the enhanced FMAP even if they opt to move an enrollee to a different benefit package group if they no longer qualify for the one in which they were enrolled so long as that package meets certain criteria (outlined below). Additionally, states would be allowed to make "programmatic changes" such as changes to the medical necessity criteria or utilization control procedures in determining coverage for benefits; elimination of optional benefits coverage; increases in cost-sharing responsibilities; and changes to the PETI methodology. The only thing states would not be able to change is the requirement for coverage of testing and treatment for COVID-19.

  The IFC outlines the three tiers of coverage permitted under this approach as the following:

  - **Tier one**: enrollees can be transitioned to any Medicaid package that meets Minimum Essential Coverage (MEC).
  - **Tier two**: enrollees can be transitioned to a non-MEC Medicaid plan as long as the benefit package is robust enough to include access to both testing and treatment for COVID-19. States will be required to transition individuals back to a tier 1 plan if they become eligible for it and are otherwise enrolled in a lesser plan.

- **Tier three**: enrollees cannot be transitioned to a non- MEC plan that is not robust enough to include COVID testing and treatment, such as TB programs and programs that only provide family planning services. For individuals that would otherwise be transferred to these minimal plans, states must instead maintain the benefit package that an individual was eligible for on March 18, 2020 unless the enrollee chooses to change. The IFC does not otherwise allow a state or territory to change someone to a tier 3 package.

The full discussion begins on p. 70.

- **Medicare Inpatient Prospective Payment System (IPPS) New COVID-19 Treatment Add-on Payment for the Remainder of the PHE** – Beginning on p. 58, CMS states it is creating a New COVID-19 Treatment Add-on Payment (NCTAP) under the IPPS for COVID-19 cases that meet certain criteria. The agency says it is doing so in order to appropriately increase payments for new drugs or biologics that become available to treat COVID-19 and prevent any financial disincentives for their use.

  The three eligibility criteria for applying the NCTAP adjustment are:

  - The case must include the use of a drug or biologic authorized to treat COVID-19. CMS notes there are only two drugs that currently meet this criterion: Veklury (remdesivir) and COVID-19 convalescent plasma.
  - The case must be eligible for the 20 percent increase in the weighting factor for the assigned MS-DRG for an individual diagnosed with COVID-19 discharged during the PHE, as established by the CARES Act.
  - The operating cost of the case must exceed the operating Federal payment under the IPPS.

  The NCTAP amount is calculated as follows – it will be equal to the lesser of:

  - 65 percent of the operating outlier threshold for the claim; or
  - 65 percent of the amount by which the costs of the case exceed the standard DRG payment (including the 20 percent add-on payment as effectuated by the CARES Act).

  An illustrative example is offered on p. 63.

- **Medicare Outpatient Prospective Payment System (OPPS) Separate Payment for New COVID-19 Treatment Policy for the Remainder of the PHE** – While no drug or biologic has received an EUA for treating COVID-19 in the outpatient setting, CMS recognizes the rapidly evolving nature of COVID-19 drug development necessitates that the agency develop policies for if and when such products exist. Current OPPS policy, outpatient drugs for treating COVID-19 could be packaged into Comprehensive Ambulatory Payment Classification (C-APC) service bundle, which would result in no separate payment for the COVID-19 treatment.

  However, CMS sees this possibility as something that would create financial disincentives for offering COVID-19 treatments in the outpatient setting. As such, CMS is creating an exception to

its OPPS C-APC policy such that any new COVID-19 treatment that meets certain criteria will always be paid separately and not packaged into a C-APC when provided on the same claim as the primary C-APC service. CMS notes this separate payment will result in an additional copayment of 20 percent of the cost of the new treatment, up to the amount of the inpatient deductible.

The two criteria for COVID-19 treatments to receive this exception follow:

- The treatment must be a drug or biologic authorized to treat COVID-19; and
- The EUA for the drug or biologic 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 and not limit its use to the inpatient setting.

See p. 63 for the full discussion.

- **Diagnostic Testing for COVID-19** – Beginning on p. 127, the U.S. Department of Health and Human Services (HHS) details that Section 6001 of the FFRCA requires group health plans and insurance issuers to provide benefits for COVID-19 diagnostic tests without cost sharing, and Section 3201 of the CARES Act amended Section 6001 to include a broader range of tests to be covered. HHS notes how testing efforts have been "hampered" due to delays in results and encourages health plans and insurance issuers to consider market-driven approaches to address the continued testing challenges. The IFC states that these approaches could include payment arrangements that create incentives for providers to reduce the time it takes to provide diagnostic test results, while still ensuring accuracy of the results in instances where it is within the ability of providers to address delays.

- **Rapid Coverage of Preventive Services for Coronavirus** – Beginning on p. 117, HHS details that Section 3203 of the CARES Act defines "qualifying coronavirus preventive service" as an item, service, or immunization, that is intended to prevent or mitigate COVID-19 and that is: 1) an evidence-based item or service that has in effect a rating of 'A' or 'B' in the current U.S. Preventive Services Task Force (USPSTF) recommendations; or 2) an immunization that has in effect a recommendation from the Advisory Committee for Immunization Practices (ACIP) for routine use. The IFC modifies this definition by removing the "routine use" requirement for ACIP recommendations to allow specific populations (as determined by ACIP) to receive an immunization as soon as it becomes available.

  HHS reiterates that Section 3203 of the CARES Act requires group health plans and health insurance issuers to cover qualifying preventive services, including COVID-19 vaccines, without cost-sharing within 15 days after the date on which an ACIP recommendation is made (p. 126).

- **Extension to the End Date of the Comprehensive Joint Replacement (CJR) Model** – Beginning on p. 98, CMS announces policy and technical changes to its CJR model. Primarily, CMS is extending the end date of its Performance Year (PY) 5 by six months, such that it will now conclude on September 30, 2021. CMS says it will continue considering adding additional performance years

to the model as outlined in its February 2020 proposed rule (details), though in the meantime says it will focus on not disrupting the model by allowing it to conclude on March 31, 2021 (the date it is currently scheduled to end). A number of additional technical changes to accommodate this extension are included throughout the remainder of the section.

- **State Innovation Waivers Policy and Regulatory Revisions in Response to the PHE for COVID-19 Public Health Emergency** – Beginning on p. 129, the Secretaries of HHS and the Department of Treasury (the Secretaries) set forth a process for states to request modifications to the public notice procedures during the PHE for COVID-19 prior to and after approval for a section 1332 waiver. HHS and the Department of Treasury acknowledge that the current Section 1332 regulations for state and federal public notice procedures and comment period requirements may impose barriers for states pursuing a proposed waiver request during PHE. To address these barriers, the Secretaries are providing the following flexibilities:

    - **Public Notice** – The Secretaries may modify, in part, the state public notice requirements and the federal public notice requirements to expedite a decision on a proposed waiver request during the PHE for COVID-19 when a delay would undermine or compromise the purpose of the proposed waiver request and be contrary to the interests of consumers. This includes waiving the requirements to hold a hearing or modifying comment periods to be less than 30 days. States must meet the requirements on p.138 to receive modifications for these requirements.

    - **Monitoring and Compliance** – The Secretaries may waive, in part, post award public notice requirements for an approved waiver during the PHE when the application of the award public notice procedures would be contrary to the interests of consumers during the PHE for COVID-19. States must meet the requirements found on p. 142.