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Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (CMS-99912-IFC)

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Summary

In response to COVID-19, the Centers for Medicare & Medicaid Services, along with the Internal Revenue Service and Employee Benefits Security Administration, released an interim final rule with request for comments (IFC). Among other policies, the IFC provides detail regarding diagnostic testing providers making public their cash prices, information on an add-on payment for new COVID-19 treatments, COVID-19 vaccine coverage and reimbursement amounts and extends the Comprehensive Care for Joint Replacement model.

Effective Date

The IFC was published on November 6, 2020 with most provisions effective on November 6, 2020 and lasting until the end of the public health emergency (PHE). Comments are due on January 4, 2021.

Provisions of the IFC – Department of Health and Human Services

Price Transparency for COVID-19 Diagnostic Tests

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) requires each provider of a diagnostic test for COVID-19 to publish online the cash price for such test during the PHE. In addition, under the CARES Act, the Secretary may impose civil monetary penalties (CMP) of up to $300/day for noncompliance. In the IFC, CMS indicates how it will monitor for noncompliance (e.g., complaints made by the public, CMS's review of providers' websites) and that it will engage in pre-penalty actions (e.g., written warning notice, request for compliance/ submission of a corrective action plan) before imposing a CMP, which providers may appeal. In addition to the cash price, in the IFC, CMS requires that providers make public a plain language description of each COVID-19 diagnostic test, the billing code(s) for each test(s), and any additional information as may be necessary for the public to be certain of the cash price for a particular COVID-19 test.

In the IFC, CMS defines a "provider of a diagnostic test for COVID-19" as "any facility that performs one or more COVID-19 diagnostic tests". CMS expects that these providers would hold a Clinical Laboratory Improvement Amendments (CLIA) certificate[1] (or have submitted CLIA application) and that such testing would occur in a variety of facilities (e.g., primacy care provider offices, urgent care centers, stand-alone national laboratories). In addition, CMS expects these providers to post the cash price on their website but, if they do not have a website, then they must make public the cash price information in writing (including email) upon request within two business days and by posting signage prominently at the location where COVID-19 tests are offered and publicly accessible. In the IFC, CMS provides flexibility for providers who do not have publicly accessible locations. CMS recognizes that obtaining a diagnostic test for COVID-19 can generally involve up to three separate health care services, including an evaluation by

[1] CLIA certification includes a Certificate of Waiver

a practitioner, specimen collection and laboratory analysis of the specimen (actual performance of the COVID-19 diagnostic test). CMS seeks comment on whether a ‘‘provider of a diagnostic test for COVID–19’’ 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 the specimen collection, if applicable.

CMS also indicates “cash price” means the charge that applies to an individual who pays in cash (or cash equivalent) for a COVID-19 diagnostic test. CMS also notes the “cash price” is analogous to the “discounted cash price” as defined under the Hospital Price Transparency final rule. It is CMS’s expectation that a provider’s “cash price” will be similar to, or lower than, rates negotiated with in-network plans and issuers. CMS solicits comment on this approach and whether any additional standards should be implemented to address any potential abuse.

CMS makes clear these requirements are immediately applicable, but does seek comment on the requirements, including the ways in which consumers request and receive COVID-19 diagnostic testing, including the site of care, frequency, and type of provider.

Medicare Inpatient Prospective Payment System (IPPS) New COVID– 19 Treatments Add-on Payment (NCTAP) for the Remainder of the Public Health Emergency (PHE)

In the IFC, CMS indicates that as drugs or biological products become available and are authorized or approved by FDA for the treatment of COVID-19 in the inpatient setting, it would be appropriate to increase the current inpatient prospective payment system (IPPS) payment amounts for these new treatments during the PHE. Therefore, effective for discharges occurring on or after November 6, 2020 and until the end of the PHE, CMS is creating a New COVID–19 Treatments Add-on Payment (NCTAP) under the IPPS for COVID-19 cases that meet certain criteria, as outlined below:

- Case must include the use of a drug or biological product authorized to treat COVID-19 and meet all Medicare coverage requirements, including it being “reasonable and necessary”;
- 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. In the IFC, CMS indicates 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. More information about the 20 percent add-on payment is available from CMS; and
- The operating cost of the case must exceed the operating Federal payment under the IPPS (including the 20 percent DRG add-on payment).

The NCTAP would 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 DRG add-on for COVID-19 cases).

Medicare Outpatient Prospective Payment System (OPPS) Separate Payment for New COVID–19 Treatments Policy for the Remainder of the Public Health Emergency (PHE)

When CMS issued the IFC, no drug or biological product had an emergency use authorization (EUA) for the treatment of COVID-19 patients in an outpatient setting.[2] Since the IFC’s release, a therapeutic was recently approved and CMS has provided related coding and billing information which are consistent with the IFC.

[2] On November 9, FDA issued an EUA for the monoclonal antibody (mAb) bamlanivimab for the treatment of mild to moderate COVID-19 in adults and pediatrics who are at high risk for progressing to severe COVID-19. However, the IFC does not provide for payment policy specific to this newly authorized biologic but does indicate the agency expects to include the addition of new codes describing COVID-19 treatment as soon as practicable, after their availability.

In the IFC, CMS aims to mitigate financial disincentives for hospitals to provide new COVID-19 treatments by pricing a separate payment for COVID-19 treatments. The payment is available for services furnished on or after November 6, 2020 and lasts until the end of the PHE. To facilitate payment, CMS is creating an exception to its Comprehensive Ambulatory Payment Classification (C-APC) packaging policy where CMS would make payments based on the primary service reported on the claim and include all other items and services on the claim as adjunctive services. Under the exception in the IFC, 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 that need to be met in addition to generally applicable Medicare requirements are that the drug/biologic is authorized to treat COVID-19, and the EUA for the drug or biologic must authorize use in the outpatient setting or not limit use to an inpatient setting.

Regarding budget neutrality, CMS explains that it does not believe it is necessary to make an adjustment to OPPS budget neutrality calculations to account for this new exception since the budgetary effect is "likely to be de minimis." However, once more claims data is available, CMS may make a prospective adjustment to the OPPS budget neutrality calculations through future rulemaking.

Temporary Increase in Federal Medicaid Funding

The Families First Coronavirus Response Act (FFCRA) and the CARES Act provides a temporary 6.2 percentage point increase to each qualifying state's Federal Medical Assistance Percentage (FMAP) ("temporary FMAP increase"). To qualify for the temporary FMAP increase in a given quarter, states must meet certain Medicaid enrollment conditions. In the IFC, CMS clarifies different aspects of the conditions, including enrollment requirements and identifies three types of coverage that must be maintained throughout the PHE (Minimum essential coverage (MEC); Non-MEC with Coverage of COVID-19 Testing and Treatment; and Non-MEC with Limited Benefits). CMS made a Medicaid fact sheet available for more information.

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

In the IFC, CMS modifies policies for certain aspects of the Comprehensive Care for Joint Replacement (CJR) model due to the impact of the PHE. In addition, CMS indicates the current COVID-19 extreme and uncontrollable circumstances policy will end on March 31, 2021 or the end of the PHE, whichever occurs first. After the Extreme and Uncontrollable Circumstances COVID-19 policy ends, actual episode payments will be capped at the quality adjusted target price for any episode with actual episode payments that include a claim with a COVID-19 diagnosis code.

Notably, in the IFC, CMS also extends Performance Year (PY) 5 of the model by an additional 6 months, until September 30, 2021. Due to the extension of PY 5, CMS will split PY 5 and perform two reconciliations – one for the first 12 months of PY 5 (PY5.1) and one for the remaining 9 months (PY5.2). The below table provides the timelines for PY 4 and 5. CMS does indicate that although the agency is implementing this extension, it will consider comments provided in response to prior proposals that aimed to extend the CJR model by three performance years.

PY	Performance Period	Initial Reconciliation	Subsequent Reconciliation	Reconciliation Amount (+/-)
4	01/01/2019 - 12/31/2019	2 months after 12/31/2019	14 months after 12/31/2019	Net PY3 and PY4 reconciliation amounts
5 (two periods)	01/01/2020 - 09/30/2021			
Subset 5.1	01/01/2020 - 12/31/2021	2 months after 12/31/2020	14 months after 12/31/2020	Net PY4 and PY5.1 reconciliation amounts
Subset 5.2	01/01/2021 - 09/30/2021	5 months after 9/30/2021	17 months after 9/30/2021	Net PY5.1 and PY5.2 reconciliation amounts

Lastly, retroactive to October 1, 2020, CMS makes a technical change to ensure the model continues to include the same inpatient Lower Extremity Joint Replacement (LEJR) procedures. As of October 1, 2020, new MS-DRGs 521 (Hip Replacement with Principal Diagnosis of Hip Fracture with Major Complications and Comorbidities (MCC)) and 522 (Hip Replacement with Principal Diagnosis of Hip Fracture, without MCC) were created and will be added to the definition of a CJR model episode. The new MS-DRGs will be incorporated into the CJR episode reconciliation data system and will be included in participant hospitals' monthly data feeds going forward.

Medicare Coding and Payment for COVID-19 Vaccine

The CARES Act established Medicare Part B coverage and payment for a COVID-19 vaccine and its administration without any beneficiary cost sharing. In doing so, the CARES Act required that an authorized or approved COVID-19 vaccine be added to the list of preventive vaccines that are covered under Medicare Part B where Part B pays 100 percent of the Medicare payment amount. Generally, in the IFC, CMS indicates the COVID-19 vaccine and its administration will be treated like other preventive vaccines and their administration (e.g., flu and pneumococcal vaccines), and makes conforming regulatory changes. In addition, after the IFC was released, CMS issued a toolkit to help stakeholders prepare to administer a COVID-19 vaccine once it is available.

However, due to the need to rapidly support vaccine access once one is authorized, CMS made changes in the IFC that are unique to the COVID-19 vaccine. For example, although CMS normally establishes Medicare payment rates through traditional rulemaking processes, due to the PHE, CMS is engaging in an expedited process. Soon after authorization or licensure of a COVID-19 vaccine by the Food and Drug Administration, CMS will announce interim coding and payment rates (and for OPPS, an APC assignment for each vaccine product's administration code). CMS will consider any product-specific costs or considerations in furnishing the service when announcing rates associated with furnishing the service, and will post information on coding, payment and billing for COVID-19 vaccines and vaccine administration on the CMS website.

In the IFC, CMS confirms that like other preventive vaccines, the Medicare allowed amount for the COVID-19 vaccine will be 95 percent of the average wholesale price (or reasonable cost under outpatient prospective payment system). However, as previously noted, the agency does anticipate establishing a unique administration code for each COVID-19 vaccine product once product-specific factors are learned.

Regarding billing processes, CMS indicates that providers and suppliers can bill Medicare for the vaccine product and the vaccine administration separately using different codes. In addition, mass immunizers may offer and bill Medicare for flu vaccinations and/or pneumococcal vaccinations to large groups of Medicare beneficiaries under roster billing. CMS also recognizes that both a one dose and two dose COVID-19 vaccination schedule can be accommodated under this approach.

Generally, Medicare Advantage (MA) plans and cost plan organizations must cover all benefits covered under Part A and Part B of Original Medicare, subject to limited exclusions. In the IFC, CMS indicates that based on certain requirements related to capitation payments made to MA plans, coverage of the COVID-19 vaccine and its administration will very likely be provided through the Medicare fee-for-service (FFS) for calendar years 2020 and 2021. As a result, MA beneficiaries will be able to access the COVID-19 vaccine, without cost-sharing, at any Medicare FFS provider or supplier that is eligible to bill for Part B vaccine administration. In addition, MA plans must cover the COVID-19 vaccine and administration without cost-sharing, based on the CARES Act. While the CARES Act did not provide similar cost-sharing protections for enrollees in cost plans who receive the vaccine from an in-network provider, CMS believes it is necessary and appropriate that cost plans comply with the same cost sharing protection available to Medicare FFS beneficiaries and MA enrollees. Therefore, CMS changes regulations to require cost plans to cover without cost-sharing for the duration of the PHE.

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

Under the FFCRA, states Medicaid programs may receive a temporary 6.2 percentage increase in their Federal Medical Assistance Percentage (FMAP) if they cover, without cost-sharing, COVID-19 testing services and treatments (including vaccines and vaccine administration). That coverage is required during any quarter for which the state claims the temporary FMAP increase, and the FMAP increase is available through the end of the quarter in which the PHE ends. In the IFC, CMS describes current policy and existing law, and with some exceptions, does not make change to current policy or regulatory requirements in the rule.

In the IFC, CMS indicates that to meet the FFCRA requirements, states must compensate Medicaid providers with a vaccine administration fee or provide reimbursement for a provider visit during which a vaccine dose is administered, even if the vaccine dose is furnished to the provider at no cost. In the IFC, CMS does note some limited exceptions to this coverage requirement, such as for individuals whose Medicaid eligibility is limited by statute to a narrow range of benefits. Additional examples of exceptions are noted in the IFC on page 8.

CMS also indicates the relevant section of the FFCRA regarding COVID-19 vaccine coverage does not apply to the Children's Health Insurance Program (CHIP) or to a state's Basic Health Program (BHP). In separate CHIPs, states must cover Advisory Committee on Immunization Practices (ACIP)-recommended vaccines and their administration for all children under age 19 with no cost-sharing. In addition, CMS notes coverage of uninsured pregnant women in a separate CHIP is optional and that vaccine coverage is not required. For states operating a BHP, coverage must include, among other benefits, all ACIP recommended vaccines without cost sharing in accordance with the Affordable Care Act as an essential health benefit.

In the IFC, CMS identifies groups that states must provide coverage of COVID-19 vaccines and their administration to after the PHE based on existing statutory and regulatory authority. These groups include Medicaid-enrolled children under 21 who are eligible for Early and Periodic Screening, Diagnostic and Treatment Benefit (EPSDT), Medicaid expansion adults covered though Alternate Benefit Plans and adults in states receiving the one-percentage FMAP increase for offering certain vaccines, among others. In addition, the state has the option to cover a COVID-19 vaccine and its administration for other eligibility groups (e.g., parent/caretaker relative eligible groups, eligible groups for individuals who are 65+ or eligible on basis of blindness or disability, and certain pregnant women). After the PHE, with some exceptions, the state has the option to apply cost sharing coverage of a COVID-19 vaccine or its administration. Also, after the PHE, a COVID-19 vaccine and its administration could also be a covered service for many Medicaid eligibility groups under certain circumstances including whether it is furnished by a participating providers and state-specific mandatory benefit characteristics.

Provisions of the IFC – Departments of the Treasury, Labor and Health and Human Services

Rapid Coverage of Preventive Services for Coronavirus

Under the CARES Act, group health plans and health insurance issuers offering non-grandfathered group or individual health insurance must cover, without cost sharing, "qualifying coronavirus preventive services"[3]. In addition, for the duration of the PHE, coverage of qualifying coronavirus preventive services must be provided no later than 15 business days following an applicable recommendation (regardless of whether it appears on the Immunization Schedules of the CDC for routine use).

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[3] Section 3203(b)(1) 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—(A) an evidence-based item or service that has in effect a rating of 'A' or 'B' in the current recommendations of the USPSTF; or (B) an immunization that has in effect a recommendation from ACIP with respect to the individual involved.

In the IFC, the Departments of the Treasury, Labor and Health and Human Services (the "Departments") clarify that as qualifying coronavirus preventive services, plans and issuers must cover, without cost sharing, COVID-19 immunizations and its administration, regardless of how the administration is billed, and regardless of whether a COVID-19 vaccine requires the administration of multiple doses. This includes coverage without cost sharing of the administration of a required preventive immunization when a third party (e.g., the federal government) pays for the immunization.

Regarding out-of-network coverage during the PHE, in the IFC, CMS makes regulatory changes to require that plans and issuers must cover, without cost sharing, a qualifying coronavirus preventive service. Such coverage is required regardless of whether it is delivered by an in-network or out-of-network provider. For rates, the IFC provides that if a provider and plan do not have a negotiated rate for such service, the plan or issuer must reimburse the provider for such service in an amount that is reasonable compared to market rates or it should be aligned with Medicare payments. The Departments request comment on the policies in this IFC, including those safeguards to ensure that out-of-network reimbursement rates are reasonable.

Diagnostic Testing for COVID-19

COVID-19 relief legislation generally requires group health plans and health insurance issuers offering group or individual health insurance coverage to provide benefits for COVID-19 diagnostic tests and certain items and services related to diagnostic testing for COVID-19. In addition, such items and services must be provided without imposing any cost-sharing requirements (including deductibles, copayments and coinsurance) or prior authorization or other medical management requirements. In the IFC, the Departments reiterate their belief that provisions in the FFCRA and the CARES Act help ensure consumers can be tested for COVID-19 without barriers related to cost, but acknowledge challenges (e.g., delays in obtaining results, issues with test accuracy and supply shortages). In the IFC, the Departments suggest a pay-for-performance arrangement, where reimbursement rates are based on the time it takes to make test results available. However, the Departments also strongly encourage plans to use safeguards to ensure the payment arrangements are not structured in a way that prioritizes speed over accuracy or that result in unintended consequences.

What's Next?

Unless otherwise specified, the IFC is effective November 6, 2020, which is when it was officially published. CMS is collecting comments until January 4, 2021.

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this IFC. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, Sr. Regulatory Affairs and Public Policy Director in Vizient's Washington, D.C. office.