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Regulatory Advisory

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Detailed Summary of Recent CMS Interim Final Rule on COVID-19 Testing and Treatment

Rule also includes COVID-19 related changes to the Comprehensive Care for Joint Replacement Model

The Centers for Medicare & Medicaid Services (CMS) Oct. 28 announced an interim final rule establishing additional Medicare hospital payment to support Medicare beneficiaries' access to COVID-19 vaccines and new treatments when they become available. CMS also released information on hospital billing for the outpatient administration of potential monoclonal antibody products; price transparency for COVID-19 tests; additional COVID-19 information relating to private health plans and Medicaid; and COVID-19-related changes to the Comprehensive Care for Joint Replacement (CJR) model. The rule also states that Medicare will cover any preventive vaccine at no cost to beneficiaries so long as it receives Food and Drug Administration approval via an emergency use authorization or Biologics License Application.

What You Can Do: Please share this advisory with your executive management team, billing department and clinical leadership team.

The following are select highlights from the documents that are important to hospitals and health systems.

Further Questions: If you have questions, please contact AHA at 800-424-4301.

Key Takeaways

This rule:

- Creates an add-on payment for inpatient cases that utilize approved or authorized COVID-19 treatments.
- Specifies that, once the FDA has authorized or approved a COVID-19 vaccine, the vaccine and its administration will be added to the list of preventive vaccines that are covered under Medicare Part B without coinsurance or deductible.
- Establishes a separate payment for FDA-approved drugs or biologicals that treat or prevent COVID-19 in the outpatient setting.
- Requires that providers of diagnostic COVID-19 tests make public their cash prices for testing.
- Requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must cover, without cost-sharing, qualifying COVID-19 preventive services.
- Clarifies guidance on the COVID-19-related enhanced FMAP and grants states greater flexibility on cost-sharing for vaccines and maintenance of enrollment requirements.
- Modifies policies related to the CJR model to attempt to account for the impact of the public health emergency on CJR participants.

HIGHLIGHTS OF THE RESOURCES

Medicare Inpatient Prospective Payment System (PPS) New COVID-19 Treatments Add-on Payment (NCTAP). The rule establishes that inpatient cases that utilize approved or authorized COVID-19 treatments will be eligible for a new add-on payment during the period of the public health emergency (PHE). Specifically, for inpatient cases meeting the criteria below, CMS will pay hospitals the lesser of (1) 65% of the operating outlier threshold for the claim or (2) 65% of the amount by which the costs of the case exceed the standard diagnosis-related group (DRG) payment, inclusive of the 20% DRG add-on for COVID-19 cases. The outlier threshold for fiscal year (FY) 2021 is approximately $30,000.

In addition, the NCTAP will *not* be included as part of the calculation of the operating outlier payments, as to prevent any inadvertent reduction in the inpatient outlier payments that the hospital would have otherwise received for a costly COVID-19 case.

The following criteria must be met in order to be eligible for the NCTAP.

- Treatment Approval/Authorization. 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 of authorization for the drug or biological product, or the drug or biological product must be approved by the FDA for treating COVID-19. Currently, only remdesivir and COVID-19 convalescent plasma meet that criteria; however, new products that meet the criteria may be eligible when they become available.

  Per the rule, the new COVID-19 treatment also would have to meet all Medicare coverage requirements, including being medically reasonable and necessary for that case.

- COVID-19 Diagnosis. The case also must be eligible for the 20% inpatient DRG add-on for COVID-19 cases during the public health emergency. Previously, CMS began to require a positive COVID-19 laboratory test documented in patients' medical records in order for inpatient claims to be eligible for the 20% add-on. See AHA's Special Bulletin for more information on the DRG add-on requirement.

- Cost of the Case. The operating cost of the case must exceed the operating Medicare payment under the inpatient PPS, inclusive of the 20% DRG add-on for COVID-19 cases. The cost would be calculated by multiplying the covered charges by the operating cost-to-charge ratio.

Medicare Coverage, Coding and Payment for COVID-19 Vaccine. This rule implements provisions of the Coronavirus Aid, Relief, and Economic Security (CARES) Act that provide that, once the FDA has authorized or approved a COVID-19 vaccine, the vaccine and its administration will be added to the list of preventive vaccines that are covered under Medicare Part B without coinsurance or deductible. Like other preventive vaccines, the Medicare allowed amount for the COVID-19 vaccine would be 95% of the average wholesale price (or reasonable cost under the outpatient PPS).

CMS ordinarily establishes Medicare payment rates for particular items and services, through notice-and-comment rulemaking. However, due to the unique circumstances of the PHE for the COVID-19 pandemic and the need to expedite the availability of COVID-19 vaccine products, it states that it plans to initially dispense with the rulemaking process. Therefore, soon after the authorization or licensure of each COVID-19 vaccine product by FDA, the agency plans to announce the interim coding and a payment rate for its administration – or in the case of the outpatient PPS, an APC assignment for each vaccine product's administration code – taking into consideration any product-specific costs or considerations involved in furnishing the service. CMS will establish specific coding and payment rates through technical direction to the Medicare Administrative Contractors (MACs) and will post information on coding, payment, and billing for COVID-19 vaccines and vaccine administration on the CMS website.

Further, to better ensure broad access to a COVID-19 vaccine, CMS plans to use billing processes for COVID-19 vaccinations that are similar to those in place for influenza and pneumococcal vaccinations. That is, the agency plans to allow COVID-19 vaccinations to be provided through the mass immunization and roster billing. CMS notes that at this time it believes that that the COVID-19 vaccines will be administered as one or two doses. CMS believes that, due to its previous pandemic influenza planning, if necessary, it will be able to accommodate a two dose COVID-19 vaccination schedule under this general approach.

Separate Outpatient PPS Payment for Outpatient COVID-19 Treatments during the PHE. In the rule, CMS notes its desire to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments in a hospital outpatient setting during the COVID-19 PHE. Therefore, CMS establishes an exception to its current packaging policy that will allow it to pay separately for FDA-approved drugs or biologicals (including blood products) authorized or approved to treat or prevent COVID-19 in the outpatient setting when they are billed on the same claim as a primary Comprehensive Ambulatory Payment Classification (C-APC) service.

This policy applies to COVID-19 treatments authorized or approved for outpatient use – which currently includes only the investigational monoclonal antibody therapy bamlanivimab. Although CMS does not expect that many beneficiaries would both receive a primary C-APC service and a drug or biological for treating COVID-19, it believes that this policy exception is necessary because such COVID-19 treatments could be administered to patients under observation, while the provider determines if the patient needs to be admitted to the hospital for COVID-19. In this case, such services would be paid through the "Comprehensive Observation Services" C-APC (C-APC 8011).

Price Transparency for COVID-19 Diagnostic Tests. This rule implements the CARES Act requirement that providers of diagnostic COVID-19 tests make public their cash prices for testing. Through this rule, the agency finalizes key definitions, details the requirements for making the prices public, and puts in place a plan for monitoring and enforcement, including civil monetary penalties. The agency codifies these requirements at 45 CFR part 182.

Definitions. In the rule, CMS defines the key terms in this requirement.

- *Diagnostic Test for COVID-19*. CMS defines a diagnostic test for COVID-19 as a COVID-19 in vitro diagnostic test for the detection of SARS-CoV-2 or diagnosis of COVID-19 (as described in section 6001 of the Families First Coronavirus Response Act (FFCRA) and amended by section 3201 of the CARES Act). CMS notes that such tests are currently billed by providers using HCPCS and CPT codes including, but not limited to: CPT codes 86408, 86409, 87635, 87426, 86328, and 86769 and HCPCS codes U0001 through U0004. This list is not exhaustive and CMS clearly states that a COVID-19 diagnostic test whose billing code is not on this list but otherwise meets the criteria may still be included in the definition. The agency expects to regularly update the list of codes through subsequent guidance, as new tests and codes are developed.
- *Provider of a diagnostic test for COVID-19.* CMS defines a provider of a diagnostic test for COVID-19 as any facility that performs one or more COVID-19 diagnostic tests (i.e., the specimen collection and laboratory analysis of the specimen). Facilities in this case could range from an outpatient hospital site to a primary care provider's office to an urgent care center to a stand-alone laboratory. CMS notes that facilities need to hold or have applied for a CLIA certification (or certification of waiver, as applicable).
- *Cash Price.* CMS defines the cash price as the "charge that applies to an individual who pays in cash (or cash equivalent) for a COVID-19 diagnostic test." This also could be referred to as the walk-in rate. The agency notes that this definition is analogous to the "discounted cash price" definition in the Hospital Price Transparency final rule (45 CFR 180.20).

CMS seeks comment on all three of these definitions. In particular, CMS asks whether the provider definition should be expanded to include all providers that perform services related to a COVID-19 diagnostic test, such as a screening visit with a primary care provider before receiving the tests. CMS also seeks comment on whether the diagnostic test definition should only include in vitro diagnostic tests and whether the cash price definition addresses stakeholders' concerns about price gouging or if a different definition would be better.

Making Cash Prices Public. CMS requires providers with public websites to post the cash prices of COVID-19 tests on their websites. The price(s) or a link to the price(s) "must appear in a conspicuous location on a searchable homepage on the provider's website." Providers that do not have a website must make their price information available in writing within two business days when requested. For the purpose of this requirement, email is considered an acceptable written format. Providers without a website that have a publicly accessible location also need to prominently post signs with the price information.

CMS requires the price information to be easily accessible and without barriers to access, such as making the consumer create a user account, submit personal identifiable information (PII), or pay a fee. In addition, CMS specifies that the provider

website homepage must contain the following keywords that will increase the likelihood that the public will be able to locate the information using a search engine: the provider's name; "price"; "cost"; "test"; "COVID"; and "coronavirus."

CMS requires that providers make the following information available, along with the cash price for each COVID-19 diagnostic test they offer:

- A plain language description of each COVID-19 diagnostic test;
- The billing code for each test; and
- Any additional information that may be necessary for the public to be certain of the cash price for a particular COVID-19 diagnostic test (e.g., location of the test).

CMS seeks comment on whether these requirements are sufficient to inform consumers about the cash price of a diagnostic test prior to receiving one, and what additional requirements may be needed to avoid consumer confusion or "prevent unintended consequences (for example, balance billing)." The agency also seeks comment on how providers should meet these requirements without deterring consumers, particularly those who are insured and face no cost-sharing for such tests. Finally, CMS asks for feedback on how to appropriately balance priorities related to price transparency and reducing barriers to COVID-19 testing.

Monitoring and Enforcement. CMS includes a plan to monitor for compliance, primarily through investigation and evaluation of complaints made by the public. In the case of non-compliance, CMS can issue a written warning notifying the provider of the violation and request that the provider submit and follow a corrective action plan (CAP). If the provider fails to submit or comply with the CAP, CMS can issue a civil monetary penalty on a provider of up to $300/day. CMS seeks comment on this approach to monitoring and enforcement.

Effective Date. These requirements are effective immediately and remain effective during the COVID-19 PHE. However, they may be revised as a result of the public comment period.

Burden Estimate. CMS estimates a one-time cost to comply with this rule of $72.62/provider. (Equal to one hour of work for a business operations specialist.) Because there are 83,309 CLIA providers that could be performing these tests, the total estimated burden of this policy is $6,049,900.

Private Health Plan Coverage of COVID-19 Vaccine. Through this rule, the Departments of Health and Human Services, Labor and Treasury implement the CARES Act requirement that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must cover, without cost-sharing, qualifying COVID-19 preventive services. This includes all doses of any approved COVID-19 vaccine, the administration of the vaccine for all required doses, and the office visit during which the vaccine is delivered. In addition, the departments confirm that during the COVID-19 PHE, private health plans must cover without cost sharing qualifying COVID-19 preventive services, regardless of whether an

in-network or out-of-network provider delivers such services. For out-of-network services, the departments require the health plans to reimburse providers at a reasonable rate. The departments note that they will consider the Medicare amount reasonable in this circumstance.

In the rule, the departments also amend existing regulations related to the timing of coverage to ensure rapid coverage of a vaccine. The change requires private health plans to cover qualifying COVID-19 preventive services (including vaccinations) within 15 business days after the date on which the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (CDC) makes an applicable recommendation relating to a qualifying coronavirus preventive service. This supersedes the standard requirement that immunizations need to be listed for routine use on the Immunization Schedules of the CDC in order to be covered. The new timing regulations sunset at the end of the COVID-19 public health crisis.

These regulations are effective immediately, but the departments seek comments on these policies, including the appropriate rate for out-of-network services.

1332 Waivers. This rule creates flexibilities in the public notice requirements and post-award public participation requirements for 1332 waivers during the COVID-19 PHE by granting the Secretaries of the Departments of Health and Human Services and Treasury authority to modify certain public notice requirements for waiver applicants and awardees. The rule establishes the process for states to request this change. This change is effective immediately and applies to the duration of the COVID-19 PHE.

Vaccine Coverage for Medicaid, CHIP, and Basic Health Plan Beneficiaries. Under the FFCRA, states are entitled to a temporary 6.2 percentage point increase in the Federal Medical Assistance Percentage (FMAP) on the condition the state covers, without cost-sharing, COVID-19 vaccines and their administration for certain Medicaid enrollees. The FMAP increase was authorized through the end of the quarter in which the PHE ends. This interim final rule clarifies previous CMS guidance on the enhanced FMAP and grants states greater flexibility with regard to cost-sharing for vaccines and maintenance of enrollment requirements.

Under the interim final rule, states are not required to cover vaccines without cost-sharing for individuals with limited Medicaid eligibility in order to be eligible for the enhanced FMAP. Examples of such populations include those who only receive Medicaid coverage for COVID-19 testing, family planning, or Tuberculosis-related treatment services. The rule also clarifies that states are not required to provide vaccine, including COVID-19, to uninsured pregnant women covered through the states' separate CHIP programs.

The rule also identifies populations for which states must provide coverage of COVID-19 vaccines even after the PHE ends. These groups include:

- Medicaid-enrolled children under age 21 who are eligible for Early and Periodic Screening, Diagnostic and Treatment Benefit (EPSDT);
- Medicaid expansion adults receiving coverage through the Alternate Benefit Plans (ABPs);
- Adults in states that elected to receive the one-percentage FMAP increase for offering vaccines under Section 1905(b) of the Social Security Act, which relates to preventive services; and
- Adults provided coverage through Basic Health Plan programs.

Medicaid Maintenance of Enrollment Requirements during the COVID-19 PHE. The interim final rule also grants states additional flexibility as it applies to requirements around maintaining Medicaid beneficiary enrollment. The FFCRA requires that states must satisfy certain Medicaid enrollment conditions in order to be eligible for the enhanced FMAP. For example, CMS previously prohibited states, as a condition of receiving the enhanced FMAP, from making any changes to beneficiary benefits or cost-sharing under post-eligibility treatment of income rules. This interim final clarifies that while states must continue to maintain the Medicaid enrollment of certain "validly enrolled beneficiaries," states do have the ability to terminate Medicaid enrollment for other beneficiaries. The agency identified three tiers of coverage that must be maintained through the PHE:

1. Minimum Essential Coverage (MEC): Medicaid coverage that meets the definition of MEC as defined by the Affordable Care Act.
2. Non-MEC with Coverage of COVID-19 Testing and Treatment: Medicaid coverage that 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.
3. Non-MEC with Limited Benefits: Medicaid coverage that does not meet the requirements of tier 1 or tier 2 because it is not MEC and does not include testing and treatment for COVID-19; examples of such limited benefit coverage include coverage available through the eligibility groups limited to family planning or tuberculosis-related services. This tier provides the least robust coverage.

Such coverage must be maintained, with some exceptions, through the end of the COVID-19 PHE. States may terminate individuals not validity enrolled after providing advance notice and fair hearing rights and still claim the temporary FMAP. States also may make changes to beneficiary coverage, cost-sharing, and post-eligibility treatment of income including individual changes, changes to the state plan, and changes to a section 1115 demonstration waiver and maintain access to the temporary enhanced FMAP. CMS provides more detailed information here.

Comprehensive Care for Joint Replacement (CJR) model. This rule modifies policies related to the CJR model that attempt to account for the impact of the PHE on CJR participants. Specifically, this rule extends performance year 5 for an additional six months, through Sept. 30, 2021. This means performance year 5 will run a total of 21 months, from Jan. 1, 2020 through Sept. 30, 2021. The agency is implementing this extension to ensure model continuity while it considers the comments to its February

2020 proposed rule which, if finalized, would extend the CJR model by an additional three performance years, through Dec. 31, 2023.

The rule also:

- Modifies the reconciliation process for performance year 5 to allow for two reconciliation periods due to the extended length of the performance year.
- Adds to the CJR model two new MS-DRGs adopted in the fiscal year 2021 inpatient PPS final rule: 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).
- Specifies that the CJR extreme and uncontrollable circumstances adjustment for COVID-19, whereby actual episode payments are capped at the quality adjusted target price determined for that episode, will end on March 31, 2021 or the last day of the emergency period, whichever is earlier. CMS originally implemented this adjustment in April, but did not specify an end date for the policy at that time. To account for patients with a positive COVID-19 diagnosis during CJR episodes that initiate after this adjustment expires, CMS also is amending its regulations to cap actual episode payments at the quality adjusted target price for the episode, effectively waiving downside risk for episodes that include a COVID-19 diagnosis.