Summary of Interim Final Rule with Request for Comment (CMS-9912-IFC)

The Centers for Medicare & Medicaid Services (CMS), issued an Interim Final Rule with Request for Comments (IFC) on Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency. Comments are due no later than **5pm on January 4, 2021**. In relevant part (pages 9-14; 35; 62-64), the IFC addresses reimbursement for COVID-19 diagnostic tests and the enforcement of the CARES Act requirement that laboratories post the cash price of their COVID-19 tests.

Cost-Sharing & Pay-for-Performance Reimbursement for COVID-19 Diagnostic Testing

The IFC reiterates that health plans are generally required to cover diagnostic testing for COVID-19 without imposing any cost-sharing requirements, prior authorization, or medical management requirements. While acknowledging that testing efforts have been hampered by supply shortages, the IFC nevertheless encourages health plans to consider "market driven approaches" to address delays in test results by exploring "payment arrangements that create incentives for providers to reduce the time it takes to provide results for diagnostic testing for COVID-19, while maintaining the accuracy rates of their test results in instances where it is within the ability of providers to address a delay."

Cash Price Posting Requirements and Enforcement

Section 3202(b) of the CARES Act requires COVID-19 diagnostic test providers to publish the cash price of their COVID-19 tests on their public website for the duration of the COVID-19 public health emergency. The IFC provides additional detail regarding this requirement and how CMS intends to enforce the requirement.

Applicable Tests. Under the IFC, the cash price posting requirement applies to molecular, antigen, and serological tests for COVID-19. Specifically, the requirement applies to all in vitro diagnostic tests for the detection of SARS-CoV-2 or diagnosis of COVID-19 and the administration of such a test that (1) Is approved, cleared, or authorized by the FDA; (2) the developer has requested, or intends to request, emergency use authorization, unless and until the emergency use authorization request 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) other tests that the Secretary of HHS determines appropriate in guidance. These tests include but are not limited to those currently billed under CPT codes 86408, 86409, 87635, 87426, 86328, and 86769 and HCPCS codes U0001-U0004.

Definition of "Cash Price." The IFC also provides more detail on what is considered the "cash price" for purposes of the cash price posting requirement. Per CMS, the cash price is the "charge that applies to an individual who pays cash (or cash equivalent) for a COVID-19 diagnostic test." Per CMS, the definition of "cash price" is analogous to "discounted cash price" as defined for the purposes of the Hospital Price Transparency Rule. Under that rule, CMS expects that "providers often offer discounts off their gross charges or make other concessions to individuals who pay for their own care" and that the cash price is generally analogous to the ""walk-in" rate that would apply to all self-pay individuals, regardless of insurance status." Per CMS, it expects that the "cash price" for COVID-19 testing will be "generally similar to, or lower than, rates negotiated with in-network plans and issuers." CMS goes further to state that "[i]f a provider has not established a "cash price" for a COVID-19 diagnostic test 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." This statement is particularly important for reference laboratories that do not provide services directly to patients. If a laboratory does not have any cash price – i.e., they do not provide testing services to those without health plan coverage or only serve as a reference laboratory for other laboratories that in turn provide patient-facing services, the laboratory should post the list price that it charges to other laboratories. If a laboratory has varying charges it charges to its reference laboratories, the laboratory should post the lowest price. Cash pricing and discounting off the gross/retail price is a significant compliance area of concern, so laboratories should check their policies and ensure that they have established a compliant price.

Website Requirements. In addition to the cash price, as defined above, CMS is also requiring laboratories to make other information available on their website. Laboratories must post in a conspicuous location on a searchable homepage of the provider's website for each COVID-19 test offered by the laboratory: 1) a plain-language description of each test, 2) the corresponding price for each test; 3) the corresponding billing code(s) for each test; and 4) any other information necessary for the public to have certainty of the cash price for each test. In addition, the provider must include all of the following terms on the laboratory's homepage: 1) the laboratory's name, 2) the term "price," 3) the term "cost," 4) the term "test," 5) the term "COVID," 6) the term "coronavirus." Certain exceptions apply for laboratories that do not have a public-facing website.

Enforcement Mechanisms. Under the IFC, CMS establishes standards for monitoring, enforcing and assessing civil monetary penalties for failure to comply with the cash price posting requirements. If a laboratory fails to comply with the requirements, CMS may issue a written warning, request that the provider submit and comply with a corrective action plan, or impose a civil monetary penalty if the provider fails to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan approved by CMS.

CMS may require a laboratory to submit a corrective action plan to CMS if the laboratory fails to come into compliance with the cash price posting requirements after a warning notice. CMS may also impose civil monetary penalties on a laboratory if CMS identifies the laboratory as noncompliant and the laboratory fails to submit a corrective action plan or fails to comply with the requirements of an approved corrective action plan.

While CMS anticipates relying predominantly on complaints by the public to identify laboratories that are not in compliance with these requirements, CMS may review an individual laboratory's website to determine compliance.