New Guidance To Implement COVID-19 Coverage Requirements And More

On April 11, 2020, the Departments of Health and Human Services (HHS), Treasury, and Labor jointly issued guidance to implement the COVID-19-related coverage provisions outlined in two recent pieces of legislation: the Families First Coronavirus Response (Families First) Act and the Coronavirus Aid, Relief, and Economic Security (CARES) Act. Collectively, these two bills require comprehensive private health insurance plans to cover COVID-19 testing and related services without cost-sharing. This post summarizes that guidance, highlights an analysis from the Congressional Budget Office (CBO), and discusses the latest efforts to shield patients from the cost of COVID-19 treatment.

What's In The Families First Act And The CARES Act?

Section 6001 of the Families First Act, as amended by the CARES Act, requires comprehensive private health insurance plans to cover testing needed to detect or diagnose COVID-19, and the administration of that testing, without cost-sharing or medical management requirements. Coverage also extends to any services or items provided during a medical visit that results in COVID-19 testing or screening. These requirements apply to group health plans (plans offered by employers) and insurers that offer individual and group health insurance coverage, including grandfathered health plans. As discussed more below, this coverage requirement is temporary.

The CARES Act enhanced the Families First requirements in three primary ways. First, the CARES Act broadened the testing that would be covered without cost-sharing beyond testing approved by the Food and Drug Administration to include tests provided by labs on an emergency basis, state-developed tests, and any other tests deemed appropriate by HHS. Second, the CARES Act attempted to help insulate patients from surprise bills for COVID-19 testing (more on that below). Third, the legislation ensured that testing and a COVID-19 vaccine will be quickly covered by insurers without cost-sharing on a permanent basis. Once recommended by expert bodies, testing and a vaccine would be covered without cost-sharing within 15 days (rather than a waiting period of at least one year for other types of preventive services).

Separately, Section 3701 of the CARES Act includes a safe harbor for high-deductible health plans (HDHPs) paired with a health savings account that begin on or before December 31, 2021 to provide pre-deductible coverage for telehealth and other remote care services. Thus, telehealth and other remote care services could be covered pre-deductible without violating federal rules for HDHPs.

CBO Analysis Of Families First

In its analysis of the Families First Act, the CBO assumed that the declared public health emergency will remain in effect for an additional 12 months (until March 2021) and that a total of 15 million COVID-19 tests will be required. Of these 15 million tests, half will be for people under age 65 who have private health insurance. (Although the testing data remains squishy, the Kaiser Family Foundation estimates that nearly 2.7 million tests have been completed so far.)

Even so, the new testing requirement will have a small impact on expenditures from 2020 to 2022. Federal outlays will increase slightly, by about $7 million, due to "a slight overall increase" in premiums in 2021. The impact of the testing provision will be slight because 1) most plans voluntarily waived cost-sharing requirements for COVID-19 tests; and 2) cost-sharing is expected to be minimal (based on cost-sharing for similar tests). This increase in premiums will decrease revenue by $4 million since higher premiums mean reduced taxable wages and higher federal subsidies in the individual market.

The CBO expects less than 10 percent of tests to be provided to uninsured people during the public health emergency and estimates much higher costs for the provisions of the Families First Act that apply to Medicare and Medicaid. CBO's analysis of the CARES Act is forthcoming.

What's In The Implementing Guidance?

The guidance includes 14 questions and answers about the new requirements under the Families First Act and the CARES Act. These questions focus on which entities must comply with the new law, what must be covered, the duration of the coverage requirement, excepted benefits, and telehealth services, among other topics. HHS issued a press release about the guidance; all CMS guidance can be found here.

Recognizing the urgency of the COVID-19 crisis, Congress authorized the Departments to implement these coverage provisions using sub-regulatory guidance. This means the changes can be implemented quickly without formal notice-and-comment rulemaking requirements. This flexibility notwithstanding, the Departments note several reasons why they believe the guidance is exempt from all or some rulemaking requirements under the Administrative Procedure Act. They believe they are announcing a statement of policy and, at a minimum, there is good cause to issue the guidance without prior public comment because soliciting comment would be impracticable and contrary to the public interest. The Departments will prioritize compliance assistance (rather than penalties) for plans working in good faith to comply with the new laws and guidance.

Scope Of Section 6001

Section 6001 applies to all group health plans and insurers offering group or individual health insurance coverage (including grandfathered health plans). The Departments confirm that this applies to fully insured and self-insured group health plans, including job-based group health plans, non-federal governmental plans (such as state and local employee health plans), and church plans. Individual health insurance coverage includes coverage sold through or outside of the marketplace (including grandmothered or transitional policies) and student health insurance coverage. This requirement does *not* extend to short-term plans, excepted benefits, or retiree-only coverage. Compliance with Section 6001 will not cause a grandfathered plan to lose its grandfathered status so long as there are no other material changes made to the plan.

Duration Of Coverage

The coverage requirements in Section 6001 are temporary. Coverage began on March 18 (when Families First was enacted) and remains in effect while there is a declared public health emergency by the Secretary of HHS (as defined under Section 319 of the Public Health Service Act). Unless extended or terminated earlier, the public health emergency related to COVID-19 (and thus the coverage requirements under Section 6001) will end onApril 25, 2020

What Must Be Covered

Section 6001 requires plans and insurers to cover items and services provided during an office visit (whether in-person or via telehealth), urgent care center visit, or emergency room visit that results in an order for or administration of an in-vitro diagnostic product for COVID-19. The covered items and services must be related to furnishing or administrating the diagnostic product (i.e., testing) or to evaluating the individual to determine whether they need the test or not (i.e., screening). The Departments provide some clarification regarding what tests, items, and services must be covered without cost-sharing or other barriers.

Serological Tests

Section 6001 includes, but is not limited to, serological tests for COVID-19. Serological tests measure the level of antibodies a person has when the body is responding to an infection such as COVID-19. Rather than detecting the virus, serological tests assess the body's immune response. Antibody tests are thus an important tool to help end the crisis by identifying those who have been infected with COVID-19 but have developed an immune response. Although serological tests should not be the sole basis for COVID-19 diagnosis at this time, plans and insurers must cover these tests (among other services) without cost-sharing under Section 6001. (More information on serological testing for COVID-19 is available here.)

Screening For Other Respiratory Illnesses

Screening for other causes of respiratory illness (such as the flu) must be covered without cost-sharing if provided during a visit that results in an order or administration of testing for COVID-19. This requirement is likely included because clinicians have been urged to test for other causes of respiratory illness before administering a COVID-19 test.

Determined By Individual Providers

All tests—whether for COVID-19 or other respiratory illnesses—must be covered without cost-sharing or other barriers when medically appropriate as determined by an attending health care provider. An attending health care provider is an individual provider who is licensed under state law and directly responsible for providing patient care. This definition, the Departments note, does *not* include a plan, insurer, hospital, or managed care company.

Thus, coverage is required if an individual provider determines that a person should be screened or tested (even if a hospital or insurer believes that the same person need not be screened or tested). This clarification should help ensure that services are covered without cost-sharing whenever a physician or other provider determines that doing so is necessary. Individual providers must make these determinations in accordance with accepted standards of current medical practice.

Non-Traditional Settings

Items and services must be covered without cost-sharing even when provided in non-traditional health care settings, such as drive-through testing centers. The Departments construe the word "visit" broadly to include both traditional and non-traditional health care settings. However, the guidance does not clarify whether cost-sharing protections extend to fees that a provider might charge due to a non-traditional (or simply a non-hospital) setting, such as a facility fee.

Surprise Bills From Out-of-Network Providers

The pandemic exacerbates current concerns about surprise medical bills and raises unique new concerns regarding COVID-19 testing and treatment. To help address potential surprise bills for COVID-19 testing, the CARES Act included a limited provision that dictates how labs and other testing providers will be reimbursed for testing. In-network providers will be paid in-network negotiated rates that were in place prior to the public health emergency. Out-of-network providers will be paid based on the provider's publicly listed "cash price" (or a lower price if the insurer can negotiate one).

The Departments summarize this statutory requirement but provide no additional guidance as to how this provision will be implemented. The guidance does not include, say, timelines for posting cash prices or any indication of whether these requirements extend beyond

diagnostic labs to the individual providers that administer the COVID-19 test.

Plans Can Make Beneficial Mid-Year Changes

Although there are some exceptions, insurers are generally not supposed to make mid-year changes to their plans. Plans or insurers that do materially change their coverage must notify enrollees at least 60 days in advance of a change. In light of the crisis (and consistent with prior guidance from HHS), the Departments will waive these requirements when plans and insurers *add* benefits or *reduce* cost-sharing for the diagnosis and treatment of COVID-19, telehealth, and other remote care services. (This flexibility does not extend to plans or insurers that attempt to *limit* benefits or *increase* cost-sharing because of COVID-19.)

Plans and insurers must still notify enrollees of changes as soon as reasonably practical (and can do so by sending an updated Summary of Benefits and Coverage or a separate notice that describes the changes). But the Departments will not take enforcement action against a plan or insurer that increases its coverage for COVID-19 or telehealth services during the declared emergency (either by HHS or President Trump). If plans or insurers maintain these changes beyond the emergency period, they must comply with all requirements regarding updated plan documents or coverage terms. HHS encourages states to adopt a similar nonenforcement stance.

States Can Go Further

The Families First Act specified that Section 6001 should apply to plans and insurers as if it was incorporated into the Public Health Service Act, ERISA, and Internal Revenue Code. Consistent with the enforcement framework under the Public Health Service Act, states can impose additional COVID-19-related standards or requirements on insurers so long as those standards do not prevent the application of federal law.

Excepted Benefits

Employers offer employee assistance programs with a wide-ranging set of benefits to improve employees' work and health. These benefits are typically offered free of charge and might include referral services for mental health counseling, financial counseling, or legal issues. Under federal regulations from 2014, employee assistance programs are deemed an excepted benefit under certain conditions (meaning they do not have to comply with the Affordable Care Act and other insurance requirements). To qualify as an excepted benefit, employee assistance programs cannot provide significant medical benefits, require premiums, or impose cost-sharing for services.

The Departments confirm that employee assistance programs can cover COVID-19 diagnosis and testing during the declared emergency (either by HHS or President Trump) without losing their status as an excepted benefit. Further, employers can cover diagnosis

and testing for COVID-19 at on-site medical clinics even though those clinics constitute an excepted benefit.

Telehealth And Other Remote Care Services

Consistent with prior guidance, the Departments encourage all plans and insurers to promote the use of telehealth and other remote care services and to cover these services without cost-sharing or other medical management barriers. They also encourage states to consider relaxing state provider licensing laws during the emergency period. A number of states have used their emergency authority to waive certain state licensing requirements, and HHS recently issued guidance to allow clinicians to practice to the full scope of their licenses.

The Departments also summarize Section 3701 of the CARES Act, which provides a temporary safe harbor for health savings account-eligible HDHPs to cover pre-deductible telehealth and other remote care services through 2022. Section 3701 also allows an HDHP enrollee to receive coverage for telehealth and other remote care services outside the HDHP and before satisfying the HDHP's deductible while still contributing to a health savings account. The changes in Section 3701 apply to all telehealth and remote care services and are not limited only to COVID-19-related services.

What About Treatment Costs For COVID-19?

The Families First Act and the CARES Act are critical first steps to addressing the costs associated with COVID-19 testing and diagnosis. But significant gaps remain, ranging from surprise medical bills to expanded subsidies for employer or individual market coverage. One area of increased attention is the need to waive cost-sharing for COVID-19 treatment (not just COVID-19 testing).

Analogizing to pneumonia-related costs, one study estimates that COVID-19 treatment costs could range from about $10,000 (for patients with no complications or comorbidities) to $20,000 (for patients with major complications or comorbidities). Another suggests that the total average charge per COVID-19 patient that needed a hospital stay would be more than $73,000. A separate analysis, commissioned by America's Health Insurance Plans, estimates that total costs of COVID-19 for commercially insured individuals could range from $44.6 billion to $438 billion over the next two years.

Insured patients would not bear the full brunt of these costs, but out-of-pocket costs could still be substantial. Since different plans have different cost-sharing configurations and actuarial values, these costs could be extensive for consumers who need treatment. While patients would be somewhat insulated by their plan's annual out-of-pocket maximum, they could face additional out-of-pocket costs due to COVID-19-related surprise medical bills.

(The White House suggests it will prohibit hospitals that receive funds under the CARES Act from sending surprise bills; this could be a powerful protection, but it is unclear how extensive this requirement will be.)

To help shield patients from high costs (particularly in a time of economic crisis), insurance regulators in a handful of states have required or encouraged insurers to waive cost-sharing for treatment, and many private insurers have done so voluntarily. (Although not a waiver of cost-sharing for treatment, Alaska recently amended its conditions-based reinsurance program to include COVID-19-related illnesses as a covered condition.)

These voluntary and state-based efforts, while critical, are not comprehensive and have led to several new federal proposals. The White House has primarily focused its efforts on coverage for the uninsured. In early April, the Trump administration hinted at a proposal to pay for COVID-19 treatment costs for the uninsured using a $100 billion fund for health care providers that was included in the CARES Act. One estimate suggests that up to 2 million uninsured people could be hospitalized with COVID-19, resulting in treatment costs of up to $41.8 billion. This would cut in substantially to the $100 billion hospital fund in the CARES Act. This new White House initiative came after criticism over not allowing a broad special enrollment period through HealthCare.gov. The Trump administration has yet to issue guidance on how this proposal will work, and key implementation questions remain.

In Congress, a comprehensive coronavirus relief package introduced by House Democrats would require group health plans and group and individual insurers (along with Medicare and Medicaid) to cover COVID-19 treatment without cost-sharing. The federal government would then reimburse insurers for the cost-sharing responsibilities under a to-be-determined payment system. This legislation would not ban surprise medical bills. In a related proposal, Sen. Bernie Sanders (I-VT) and Rep. Pramila Jayapal (D-WA) would direct Medicare to pay health care costs (including COVID-19-related treatment) for the uninsured and out-of-pocket costs for those with public or private health insurance. This legislation would ban balance billing by providers that accept the funds and prohibit private insurers from increasing cost-sharing or decreasing coverage in the meantime. This coverage would extend until a COVID-19 vaccine is approved by the FDA and made available to the public.