



WEST VIRGINIA INSURANCE BULLETIN

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Insurance Bulletins are issued when the Commissioner renders formal opinions, guidance or expectations on matters or issues, explains how new statutes or rules will be implemented or applied, or advises of interpretation or application of existing statutes or rules.

► At-Home COVID-19 Testing Kits ◀

The Offices of the Insurance Commissioner (OIC) has received questions from consumers and insurance companies regarding coverage for at-home COVID-19 testing kits. Specifically, both insurance companies and consumers have asked whether health plans and health insurance issuers are required to cover at-home COVID-19 testing kits when an individual has not engaged with a healthcare provider directly or in-person.

On March 18, 2020, the United States Congress enacted the *Families First Coronavirus Response Act* (FFCRA). Section 6001 of the FFCRA generally requires group health plans and health insurance issuers offering group or individual health insurance coverage to provide benefits related to diagnostic testing for the detection of COVID-19 on or after March 18, 2020, and during the applicable emergency period which has not yet expired. Under the FFCRA, plans and insurers must provide this diagnostic testing coverage without imposing any cost-sharing requirements including deductibles, copayments and coinsurance, or prior authorization or other medical management requirements. On March 27, 2020, the United States Congress enacted the *Coronavirus Aid, Relief and Economic Security Act*, (CARES Act). Section 3201 of the CARES Act amended section 6001 of the FFCRA to include a broader range of diagnostic items and services that must be covered without any cost-sharing requirements, prior authorization or other medical management requirements. This coverage must be provided when medically appropriate as determined by an individual's attending healthcare provider and in accordance with accepted standards of medical practice.

On June 23, 2020, the Department of Labor (DOL), the Department of Health and Human Services (HHS), and the Department of the Treasury (collectively "Departments") issued additional formal guidance regarding implementation of the FFCRA and CARES Act. As part of that guidance, the Departments clarified that,

COVID-19 tests intended for at-home testing, including tests where an individual performs self-collection of a specimen at home, must be covered when the test is ordered by an attending healthcare provider who has determined that the test is medically appropriate for the individual based on accepted standards of medical practice and the test otherwise meets the statutory criteria in section 6001(a)(1) of the FFCRA.

Consistent with section 6001 of the FFCRA, this coverage must be provided without imposing any cost-sharing requirements, prior authorization, or other medical management requirements.

Generally, to meet the statutory criteria in section 6001(a) of the FFCRA, the at-home test must have received an Emergency Use Authorization (EUA) under the Federal Food, Drug, and Cosmetic Act from the Food and Drug Administration (FDA) or the developer must have requested, or intends to request, an EUA from the FDA, provided that the developer's EUA request has not been denied and that the developer has submitted the EUA request within a reasonable timeframe. In the latter scenario, the plan or insurer may take reasonable

or necessary steps to verify that a test offered by a developer meets statutory criteria for an EUA and any reasonable or necessary verification requests will not be considered to violate FFCRA section 6001's prohibition on medical management requirements.

Further, the recent guidance clarified that, to be considered an attending healthcare provider, the provider does not need to be directly responsible for providing care to an individual so long as the provider makes an individualized, clinical assessment to determine whether the test is medically appropriate in accordance with accepted standards of medical practice. An attending healthcare provider for purposes of section 6001 of the FFCRA is an individual who is licensed or authorized, acting within the scope of his or her license or authorization, and is responsible for providing care to the patient.

The OIC has determined that, in certain circumstances, an attending healthcare provider may not directly engage or interact with an individual when an at-home COVID-19 testing request is being evaluated by a laboratory or test developer. However, an at-home COVID-19 testing kit must be covered by an insurer without imposing any cost-sharing requirements, prior authorization, or other medical management requirements on the individual covered under the plan or policy when:

1. The individual requesting the test undergoes a valid screening or eligibility assessment;
2. The screening or eligibility assessment is reviewed and evaluated by a licensed healthcare provider;
3. The licensed healthcare provider is acting within the scope of his or her license; and,
4. The licensed healthcare provider authorizes or orders the at-home COVID-19 test for the individual.

This guidance is being issued due to the State's urgent need to combat the public health emergency posed by COVID-19 and given the critical importance of expanding the availability of COVID-19 testing through safe and accurate testing options. Due to the extraordinary circumstances of the COVID-19 pandemic, insurers are to give deference to a healthcare provider's clinical judgment as to whether the testing is medically appropriate. However, a healthcare provider must be involved, even if only remotely, virtually and/or indirectly through review/assessment, in the determination that an at-home COVID-19 diagnostic test is medically appropriate for the test to be covered without the imposition of any cost-sharing requirements, prior authorization, or other medical management requirements.

Please note that the provisions of this Insurance Bulletin, while applicable to COVID-19 testing generally, do not override or supersede the State mandates regarding coverage of testing set forth in the Commissioner's *Emergency Order 20-EO-07* or *Emergency Order 20-EO-08*. Further, nothing in the FFCRA or the CARES Act prevents a state from imposing additional standards or requirements on health insurers with respect to the diagnosis or treatment of COVID-19 so long as the state's standards or requirements do not prevent the application of a federal requirement.

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