THE WAGNER LAW GROUP

LAW ALERT
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Agencies Issue Guidance on Coronavirus Diagnostic Testing and Immunizations

Section 6001 of the Families First Coronavirus Response Act (FFCRA) required group health plans and health insurance issuers to provide coverage for certain items and services including in vitro diagnostic testing products for the detection of the virus that causes COVID-19, or for the diagnosis of COVID-19 when those items or services are offered on or after March 18, 2020, and during the public health emergency for COVID-19. Section 3201 of the CARES Act amended Section 6001 of the FFCRA to include a broader range of diagnostic tests that health plans and issuers must cover. This coverage must be provided without any cost sharing, prior authorization, or other medical management requirements.

HHS, DOL, and IRS (the "Agencies") have issued interim final regulations (as well as proposed regulations mirroring the interim final regulations) modifying current regulations addressing coverage of preventive services without cost sharing under Section 2713 of the Public Health Service Act (PHSA), which was added by the Affordable Care Act to implement the unique requirements related to rapid coverage of qualifying coronavirus preventive services under Section 3203 of the CARES Act. (Section 2713 of PHSA does not apply to grandfathered group health plans or retiree-only plans). The regulations provide that during the public health emergency for COVID-19, health plans and issuers must cover, without cost sharing, qualifying coronavirus preventive services, regardless of whether such services are delivered by an in-network or out-of-network provider. The coverage is required to be provided within 15 business days after the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices makes an applicable recommendation relating to a qualifying coronavirus preventive service. Plans and issuers subject to Section 2713 of the PHSA must cover, without cost-sharing, recommended immunizations, as well as administration of such immunizations, regardless of how the administration is billed. The regulations also define qualifying coronavirus preventive services in a manner consistent with the CARES Act, and clarify that plans and issuers subject to Section 2713 of the PHSA must cover recommended immunizations for COVID-19 that are qualifying coronavirus preventive services, even if not listed for routine use on the immunization schedules of the Centers for Disease Control. These interim final regulations were effective on November 2, 2020, and will continue for the duration of the public health emergency.

The Centers for Medicare & Medicaid (CMS) has issued interim final regulations under Section 3202(b)(1) of the CARES Act, which requires that during the public health emergency, providers of COVID-19 diagnostic tests make public the cash price for such tests on a public Internet Website of such provider. Under the CMS regulations, cash price means the charge that applies to an individual who pays cash or cash equivalent for a COVID-19 diagnostic test; a COVID-19 diagnostic test is defined as a COVID-19 in vitro diagnostic test as described in Section 6001 of the Family First Coronavirus Response Act as amended by Section 3201 of the Cares Act; and the provider of a diagnostic test for COVID-19 in any facility that performs one or more COVID-19 diagnostic tests. These regulations will continue during the duration of the public health emergency.

The following information must be made public: (i) a plain language description of each COVID-19 diagnostic test that is offered by the provider; (ii) the billing code used for each COVID-19 diagnostic test; (iii) the provider's cash price for each COVID-19 diagnostic test; and (iv) any additional information that may be necessary for the public to have certainty of the cash price that applies to each COVID 19-diagnostic test. The information described in the preceding sentence, or a link to such information, must appear in a conspicuous location on

a searchable homepage of the provider's Website. Additionally, the information must be described in a manner that is easily accessible, without barriers, and ensures that the information is accessible free of charge, without having to establish a user account or password, and without having to submit personal identifiable information. Also, the provider's homepage must include the following items: (i) the provider's name; (ii) the term price; (iii) the term cost; (iv) the term test; (v) the term COVID; and (vi) the term coronavirus. A provider of a coronavirus diagnostic test that does not have its own Website is required to make its information public in writing, within two business days upon request, and on a sign posted prominently at the location where a provider offers a COVID-19 diagnostic test, if such location is accessible to the public.

CMS has responsibility for monitoring and enforcement of the requirement that during the public health emergency, providers of COVID-19 diagnostic tests make public their cash price, and its actions to address noncompliance include the assessment of a $300 per day civil penalty, if the provider fails to respond to the request of CMS to submit a corrective action plan (described in the regulations) or to comply with the requirements of a corrective action plan approved by CMS.

The modifications to the regulations dealing with coverage of preventive services without cost sharing is consistent with the FAQs issued by the Agencies in April, although the regulations address issues not answered in the FAQs, such as whether coverage of coronavirus diagnostic tests without cost sharing was limited to in-network providers, or applied to out-of-network providers as well. The interim final regulations dealing with the public posting of cash prices, are a new item, not addressed in the April guidance.

Sponsors of group health coverage will need to note that coverage of COVID-19 diagnostic tests from out-of-network providers will still be subject to cost sharing. Further, the rules on public posting of cash prices should provide necessary information for participants on the costs of such testing. Please contact a member of The Wagner Law Group's Welfare Plan Practice Group for more information.

Please visit our COVID-19 page, for additional resources related to COVID-19.

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