

# **COVID-19 and Private Health Insurance Coverage: Frequently Asked Questions**

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## **COVID-19 and Private Health Insurance Coverage: Frequently Asked Questions**

There is considerable congressional interest in understanding private health insurance coverage of health benefits related to the ongoing Coronavirus Disease 2019 (COVID-19) pandemic. This report addresses frequently as ked questions about private health insurance covered benefits and consumer cost sharing related to COVID-19 testing, treatment, and vaccination. It explains relevant legislation enacted in 2020, references existing federal requirements, discusses applicable administrative guidance, and notes state and private-sector actions.

Federal and state health insurance requirements may relate to covered benefits and consumer cost sharing, among many other topics. These requirements can vary by coverage type (i.e., individual coverage, fully insured small- and large-group coverage, and self-insured plans). Covered benefits, consumer costs, and other plan features may vary by plan within each type of coverage, subject to applicable federal and state requirements.

The following bullets summarize federal requirements related to coverage and cost sharing (which includes deductibles, coinsurance, and copayments) of COVID-19 testing, treatment, and vaccination. Additional details are addressed in the report, including the applicability of the requirements to different types of plans; whether the coverage requirements apply even when furnished by out-of-network providers; whether plans are allowed to impose prior authorization or other medical management techniques; and the applicable dates of any coverage requirements.

- **COVID-19 Testing.** The Families First Coronavirus Response Act (FFCRA; P.L. 116-127), as amended by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act; P.L. 116-136), requires most private health insurance plans to cover COVID-19 testing, administration of the test, and related items and services, as defined by the acts. This coverage must be provided without consumer cost sharing.
- **COVID-19 Treatment.** There are no federal requirements that specifically require coverage of COVID-19 treatment. However, the existing federal requirement that certain plans cover a set of 10 categories of essential health benefits (EHB) is potentially relevant to coverage of COVID-19 treatment items and services, depending on state and plan variation with regard to implementation of this requirement. Even where treatment items and services are required to be covered as EHB, cost sharing could apply.
- **COVID-19 Vaccination.** For a nation wide vaccination campaign, the federal government has purchased, and is making available to providers at no cost, all COVID-19 vaccines and certain related supplies. Given this federal purchase, applicable plans still must cover providers' vaccine administration fees without consumer cost sharing. This is related to a CARES Act requirement for most plans to cover recommended COVID-19 vaccines without consumer cost sharing. Most plans also must cover, without cost sharing, other COVID-19 preventive services that may be recommended, as specified by the CARES Act.

Some states also have announced relevant requirements on the plans they regulate, and some insurers have reported that they will cover certain relevant benefits. Several organizations are tracking these announcements, as noted in this report.

Congressional Research Service (CRS) experts on other topics related to private health insurance and COVID-19, including types of plans and coverage of benefits not addressed in this report, are listed in the **Appendix** for the benefit of congressional clients. For information on other COVID-19 is sues, congressional clients can access the CRS Coronavirus Disease resources page at https://www.crs.gov/resources/coronavirus-disease-2019.

#### SUMMARY

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## Introduction

The Coronavirus Disease 2019 (COVID-19) pandemic continues in 2021. As private health insurance is the predominant source of health coverage in the United States,<sup>1</sup> there is considerable congressional interest in understanding private health insurance coverage of health benefits related to COVID-19 diagnosis, treatment, and prevention.

This report addresses frequently asked questions about covered benefits and consumer cost sharing related to COVID-19 testing, treatment, and vaccination. It explains relevant legislation enacted in 2020, references existing federal requirements, discusses applicable administrative guidance, and notes state and private-sector actions. It begins with background information on types and regulation of private health insurance plans.

The Families First Coronavirus Response Act (FFCRA; P.L. 116-127)<sup>2</sup> requires specified types of private health insurance plans to cover COVID-19 testing, administration of the test, and related items and services, without consumer cost sharing. The Coronavirus Aid, Relief, and Economic Security Act (CARES Act; P.L. 116-136)<sup>3</sup> further addresses private health insurance coverage of COVID-19 testing, and requires coverage of COVID-19 vaccines and other preventive services without cost sharing, if they are recommended by specified federal entities. Given the subsequent federal purchase of all COVID-19 vaccines and certain related supplies, applicable plans still must cover providers' vaccine administration fees without consumer cost sharing. There are no federal requirements that specifically require coverage of COVID-19 treatment services. However, one or more existing federal requirements are potentially relevant, as discussed in this report. Some states also have announced requirements related to covered benefits and consumer costs, and some insurers have reported that they will voluntarily cover certain relevant benefits.

This report discusses most U.S. private health insurance plans' coverage of health care items and services related to COVID-19, but it generally does not discuss the delivery of those services, insurers' payments to health care providers, or private health insurance coverage of other benefits. The **Appendix** lists Congressional Research Service (CRS) analysts who can discuss with congressional clients other topics of interest related to private health insurance and COVID-19, including types of plans and coverage of benefits not addressed in this report. Also beyond the scope of this report are public health coverage programs (e.g., Medicare); the domestic and international public health responses to COVID-19; and economic, human services, and other nonhealth issues. For further information on these topics, congressional clients can access the CRS Coronavirus Disease 2019 resources page at https://www.crs.gov/resources/coronavirus-disease-2019.

The information in this report is current as of its publication date and may be superseded by subsequent congressional or administrative action. Congressional clients may contact the report author and/or the experts listed in the **Appendix** for questions about further developments. In

<sup>&</sup>lt;sup>1</sup> For more information and coverage estimates, see CRS In Focus IF10830, U.S. Health Care Coverage and Spending.

<sup>&</sup>lt;sup>2</sup> H.R. 6201 was signed into law as the Families First Coronavirus Response Act (FFCRA; P.L. 116-127) on March 18, 2020. See CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*, for more information about the health provisions in the act.

<sup>&</sup>lt;sup>3</sup> H.R. 748 was signed into law as the Coronavirus Aid, Relief, and Economic Security Act (CARES Act; P.L. 116-136) on March 27, 2020. See CRS Report R46334, *Selected Health Provisions in Title III of the CARES Act (P.L. 116-136)* for more information about the health provisions in the act.

addition, Centers for Medicare & Medicaid Services (CMS) guidance related to private health insurance and COVID-19 is compiled on its website.<sup>4</sup>

## **Background on Private Health Insurance**

The private health insurance market includes both the *group market* (largely made up of employer-sponsored insurance) and the *nongroup market* (commonly referred to as the individual market, which includes plans directly purchased from an insurer). The group market is divided into small- and large-group market segments; a *small group* is typically defined as a group of up to 50 individuals (e.g., employees), and a *large group* is typically defined as one with 51 or more individuals.<sup>5</sup> Employers and other group health plan sponsors may purchase coverage from an insurer in the small- and large-group markets (i.e., they may *fully insure*). Sponsors may instead finance coverage themselves (i.e., they may *self-insure*).<sup>6</sup> The individual and small-group markets include plans sold on and off the individual and small-group health insurance exchanges, respectively.<sup>7</sup>

Covered benefits, consumer costs, and other plan features may vary by plan, subject to applicable federal and state requirements. The federal government may regulate all the coverage types noted above (i.e., individual coverage, fully insured small- and large-group coverage, and self-insured group plans), and states may regulate all but self-insured group plans. Federal and state requirements may vary by coverage type.<sup>8</sup>

This report focuses on private-sector plans explained above.<sup>9</sup> There are some variations of these coverage types, and there are other types of private health coverage arrangements, which may or may not be subject to the requirements discussed in this report, or for which there may be other policy questions related to COVID-19. These other coverage types are out of the scope of this report, but a number of them are identified in the **Appendix**, along with resources for further information.

One coverage variation, *grandfathered plans*, is included in this report because it is explicitly referenced in legislation relevant to COVID-19 and private health insurance coverage. Grandfathered plans are individual or group plans in which at least one individual was enrolled as

<sup>&</sup>lt;sup>4</sup> See Centers for Medicare & Medicaid Services (CMS), The Center for Consumer Information and Insurance Oversight (CCIIO), "Coronavirus Disease 2019 (COVID-19) Guidance," accessed March 22, 2021, at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs#COVID-19.

<sup>&</sup>lt;sup>5</sup> In general, for purposes of health insurance requirements, small groups are those with 50 or fewer individuals (e.g., employees). States can also define them as having 100 or fewer individuals. The definition of large group is 51 or more individuals, or 101 or more individuals, depending on the definition of small group.

<sup>&</sup>lt;sup>6</sup> Employers and other plan sponsors may purchase coverage from state-licensed insurers and offer it to their employees or other group members. Employers and other plan sponsors that obtain health insurance plans in this way are referred to as being *fully insured*. Employers or other plan sponsors that *self-insure* set aside funds to pay for health benefits directly, and they bear the risk of covering medical expenses generated by the individuals covered under the self-insure plan.

<sup>&</sup>lt;sup>7</sup> The health insurance exchanges are virtual marketplaces in which consumers and small businesses can shop for and purchase private health insurance coverage. For more information, see CRS Report R44065, *Overview of Health Insurance Exchanges*.

<sup>&</sup>lt;sup>8</sup> For more information about types of plans and regulation of them, see CRS Report R45146, *Federal Requirements on Private Health Insurance Plans.* 

<sup>&</sup>lt;sup>9</sup> In terms of group coverage, this report focuses on group plans sponsored by private-sector employers and other sponsors. Some information in this report may also apply to federal, state, and local government employee group plans. See the **Appendix** for resources on federal employee and other types of government plans.

of enactment of the Patient Protection and Affordable Care Act (ACA; P.L. 111-148, as amended), and which continue to meet certain criteria.<sup>10</sup> Plans that maintain their grandfathered status are exempt from some, but not all, federal requirements.

Another type of coverage, *short-term, limited duration insurance* (STLDI or STLD plans), is also included in this report, because it is explicitly excluded from a coverage definition cited by relevant legislation. STLDI is coverage, generally sold in the individual market, which meets certain definitional criteria. The statutory definition of "individual health insurance coverage" excludes STLDI; thus, STLDI is exempt from complying with all federal health insurance requirements applicable to individual health insurance plans.<sup>11</sup>

## FAQ: COVID-19 Covered Benefits and Cost Sharing

The remainder of this report addresses private health insurance coverage of COVID-19 testing, treatment, and vaccination. Where there are federal requirements related to such coverage, it is useful to understand the following:

- Is the service or item required to be covered? If so, is cost sharing allowed? In general, private health insurance cost sharing includes deductibles, coinsurance, and copayments.<sup>12</sup>
- Are plans allowed to impose prior authorization or other medical management requirements? For example, some insurers require enrollees to obtain prior authorization from the insurer for routine hospital inpatient care, and/or require that primary care physicians provide approval or referrals for specialty care, as a condition for covering the care.<sup>13</sup>
- Does the coverage requirement depend on how or where the service or item is furnished (e.g., by an *in-network* versus *out-of-network* provider)? Under private insurance, benefit coverage and consumer cost sharing is often contingent upon whether the service or item is furnished by a provider that the insurer has contracted with (i.e., whether that provider is in network for a given plan). In instances where a contract between an insurer and provider does not exist, the provider is considered out of network.<sup>14</sup>
- When is the coverage requirement in effect?
- What types of plans are subject to the coverage requirement?

To the extent that information is available, these issues are addressed with regard to private health insurance coverage of COVID-19 testing, treatment, and vaccination. **Table 1** summarizes key information.

<sup>&</sup>lt;sup>10</sup> The ACA was enacted on March 23, 2010. For more information about grandfathered plans, see CRS Report R46003, *Applicability of Federal Requirements to Selected Health Coverage Arrangements*.

<sup>&</sup>lt;sup>11</sup> See 42 U.S.C. §300gg-91(b)(5). For more information about STLDI, see the report cited in footnote 10.

<sup>&</sup>lt;sup>12</sup> A *deductible* is the amount an insured consumer pays for covered health care services before coverage begins (with exceptions). *Coinsurance* is the share of costs, figured in percentage form, an insured consumer pays for a covered health service. A *copayment* is the fixed dollar amount an insured consumer pays for a covered health service.

<sup>&</sup>lt;sup>13</sup> For more information, see the appendix of CRS Report RL32237, Health Insurance: A Primer.

<sup>&</sup>lt;sup>14</sup> For more information, see the background section of CRS Report R46116, *Surprise Billing in Private Health Insurance: Overview and Federal Policy Considerations.* 

|   | Coverage and Cost-Sharing<br>Requirements   | Medical<br>Management<br>Approaches<br>Allowed? <sup>a</sup> | Applies<br>Out-of-<br>Network? <sup>b</sup> |   | Group Market <sup>c</sup>   |                             |                               |                                   |
|---|---|--|---|---|-----------------------------|-----------------------------|-------------------------------|-----------------------------------|
| Authority   |   |  |   | Time Frame  | Fully Insured <sup>e</sup>  |                             | Self-<br>Insured <sup>f</sup> | Individual<br>Market <sup>d</sup> |
|   |   |  |   |   | Large<br>Group <sup>g</sup> | Small<br>Group <sup>g</sup> |                               |                                   |
| Testing   |   |  |   |   |                             |                             |                               |                                   |
| FFCRA §6001<br>(as amended by<br>CARES Act §3201)                                       | COVID-19 testing, administration of the test,<br>and related items and services, as defined, must<br>be covered without cost sharing.   | Prohibited.  | Yes.  | FFCRA enactment<br>(March 18, 2020)<br>through declared<br>COVID-19 PHE. <sup>h</sup>   | √ (+GF) <sup>i</sup>        | √ (+GF) <sup>i</sup>        | √ (+GF) <sup>i</sup>          | √ (+GF) <sup>i</sup>              |
| Treatment   |   |  |   |   |                             |                             |                               |                                   |
| 42 U.S.C. §18022;<br>CMS March 5,<br>2020, and March<br>12, 2020, guidance <sup>j</sup> | EHB requirements <i>may</i> apply to coverage of COVID-19 treatment services, <i>subject to</i> state and plan variation. Cost sharing is possible and may vary by plan.  | Allowed; may<br>vary by plan.                                | No.   | Permanent; existed<br>prior to COVID-19<br>pandemic.  | N.A.                        | $\checkmark$                | N.A.                          | $\checkmark$                      |
| 42 U.S.C. §18022  | Where EHB requirements are applicable,<br>certain other requirements are also applicable,<br>such as the limit on annual out-of-pocket<br>spending on EHB benefits.   | N.A.   | No.   | Permanent; existed<br>prior to COVID-19<br>pandemic.  | √k                          | $\checkmark$                | √k                            | $\checkmark$                      |
| Vaccination   |   |  |   |   |                             |                             |                               |                                   |
| CARES Act §3203;<br>November 2020<br>IFR <sup>1</sup>                                   | COVID-19 vaccination items and services, and<br>other COVID-19 preventive items and services,<br>must be covered without cost sharing if<br>recommended by ACIP or the USPSTF. <sup>m</sup><br>Given the federal purchase of all vaccines, plans<br>must still cover vaccine administration fees<br>without cost sharing. | Allowed; may<br>vary by plan.                                | Only during<br>declared<br>COVID-19<br>PHE. | 15 business days after<br>ACIP or USPSTF<br>recommendation;<br>general coverage<br>requirements not<br>limited to declared<br>COVID-19 PHE. | 1                           | 1                           | V                             | $\checkmark$                      |

#### Table 1. Applicability of Federal COVID-19 Coverage Requirements to Private Health Insurance Plans

Source: CRS analysis of relevant legislation, statute, regulation, and guidance.

**Notes:** Checkmark ( $\checkmark$ ) = requirement is applicable to that plan type. The variation ( $\checkmark$ +GF) = requirement also is applicable to grandfathered plans; see table note (i). N.A. = requirement is not applicable to that plan type. None of these requirements applies to short-term, limited-duration insurance (STLDI); see table note (d). ACIP = Advisory Committee on Immunization Practices; CARES Act = Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136); EHB = essential health benefits; FFCRA = Families First Coronavirus Response Act (P.L. 116-127); PHE = COVID-19 public health emergency; see table note (h); USPSTF = United States Preventive Services Task Force. The requirements listed in the table do not comprise a comprehensive list of all federal requirements that apply to all health plans.

- a. An example of a medical management technique that insurers may use, as allowed, is requiring enrollees to obtain prior authorization from the insurer for coverage of certain services. For more information, see the appendix of CRS Report RL32237, *Health Insurance: A Primer*.
- b. All requirements apply to services or items furnished in network. Under private insurance, benefit coverage and consumer cost sharing are often contingent upon whether a service or item is furnished by a provider that the insurer has contracted with (i.e., whether that provider is *in network* for a given plan). In instances where a contract between an insurer and provider does not exist, the provider is considered *out of network*. For more information, see the background section of CRS Report R46116, Surprise Billing in Private Health Insurance: Overview and Federal Policy Considerations.
- c. Health insurance may be provided to a group of people who are drawn together by an employer or other organization, such as a trade union. Such groups generally are formed for purposes other than obtaining insurance, such as employment. When insurance is provided to a group, it is referred to as group coverage or group insurance. In the group market, the entity that purchases health insurance on behalf of a group is referred to as the plan sponsor.
- d. Consumers who are not associated with a group can obtain health coverage by purchasing it directly from an insurer in the individual (or nongroup) health insurance market. Although STLDI is a type of coverage generally sold in the individual market, the statutory definition of individual health insurance coverage excludes STLDI. Thus, no federal health insurance requirements on individual health insurance plans apply to STLDI.
- e. A fully insured health plan is one in which the plan sponsor purchases health coverage from a state-licensed insurer; the insurer assumes the risk of paying the medical claims for benefits covered under the health plan of the sponsor's enrolled members.
- f. Self-insured plans refer to health coverage that is provided directly by the organization sponsoring coverage for its members (e.g., a firm providing health benefits to its employees). Such organizations set aside funds and pay for health benefits directly. Under self-insurance, the organization bears the risk for covering medical claims. In general, the size of a self-insured employer does not affect the applicability of federal requirements.
- g. In general, for purposes of health insurance requirements, small groups are those with 50 or fewer individuals (e.g., employees). States can also define them as having 100 or fewer individuals. The definition of large group is 51 or more individuals, or 101 or more individuals, depending on the definition of small group.
- h. Some FFCRA and CARES Act coverage requirements are contingent upon the declaration of the COVID-19 public health emergency. This was declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective as of January 27, pursuant to Section 319 of the Public Health Service Act. Hence, the emergency period began on January 27, 2020, and remains in effect as long as the declaration, or any renewal of it, is in effect. See "Duration of Emergency Period" in CRS Report R46316, Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127; and HHS, Assistant Secretary for Preparedness and Response, "Public Health Emergency Declarations," at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.
- i. Grandfathered plans are individual or group plans in which at least one individual was enrolled as of enactment of the Patient Protection and Affordable Care Act (ACA; P.L. 111-148, as amended), and which continue to meet certain criteria. Plans that maintain their grandfathered status are exempt from some federal requirements. However, FFCRA specifies that its COVID-19 testing coverage requirements *do* apply to grandfathered plans.
- j. Centers for Medicare & Medicaid Services (CMS), "FAQs on Essential Health Benefit Coverage and the Coronavirus (COVID-19)," March 12, 2020. CMS, "Information Related to COVID-19 Individual and Small Group Market Insurance Coverage," March 5, 2020.
- k. Self-insured plans and plans offered in the large-group market must comply with this requirement even though they are not required to cover the EHB. HHS has indicated that such plans must use a permissible definition of EHB to determine whether they comply with the requirement.
- I. Departments of Labor, HHS, and the Treasury, "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency," 85 Federal Register 71142, November 6, 2020, at https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-tothe-covid-19-public-health-emergency.
- m. See "Are Plans Required to Cover COVID-19 Vaccination?" regarding COVID-19 vaccines available as of the date of this report. Cost sharing for office visits associated with applicable vaccinations and other preventive services may or may not be allowed. In general, this depends on whether the preventive service or item was the primary purpose of the visit, and whether the service or item was billed or tracked separately from the office visit. See 45 C.F.R. §147.130(a)(2).

## Are Plans Required to Cover COVID-19 Testing?

### FFCRA and CARES Act

Prior to the enactment of the FFCRA, there were no federal requirements specifically mandating private health insurance coverage of items or services related to COVID-19 testing.

Section 6001 of the FFCRA, as amended, requires most private health insurance plans to cover COVID-19 testing, administration of the test, and related items and services, as defined in the act. The coverage must be provided without consumer cost sharing, including deductibles, copayments, or coinsurance. Prior authorization or other medical management requirements are prohibited.<sup>15</sup> The Department of Labor (DOL), Department of Health and Human Services (HHS), and Treasury issued FAQ documents on April 11, 2020,<sup>16</sup> June 23, 2020,<sup>17</sup> and February 26, 2021,<sup>18</sup> (hereinafter "Tri-Agency FAQ 42," "Tri-Agency FAQ 43," and "Tri-Agency FAQ 44," respectively) on the private health insurance coverage requirements in FFCRA and the CARES Act.<sup>19</sup>

#### Types of Tests, Related Items and Services, and Testing Settings

FFCRA Section 6001(a)(1), as amended by the CARES Act Section 3201, describes the types of tests that must be covered, along with the administration of such tests. Together, the acts require coverage of in-vitro diagnostic tests (as defined in Food and Drug Administration [FDA] regulation)<sup>20</sup> that detect SARS-CoV-2 or diagnose the virus that causes COVID-19 and are approved, cleared, or authorized for marketing by the agency or being marketed or clinically used pursuant to an allowed flexibility in FDA guidance. The acts did not explicitly state whether this included serology testing.<sup>21</sup> The Tri-Agency FAQ 42 interpreted the coverage requirement as applying to diagnostic (i.e., molecular and antigen) and serological (i.e., antibody) tests.

Together, the acts, as interpreted by the agencies through guidance, also require coverage without cost sharing of

<sup>&</sup>lt;sup>15</sup> See the introduction to this section regarding cost sharing and prior authorization requirements.

<sup>&</sup>lt;sup>16</sup> Department of Labor (DOL), HHS, and Treasury, "FAQS About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation, Part 42," April 11, 2020, at

https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf. Hereinafter referred to as Tri-Agency FAQ 42.

<sup>&</sup>lt;sup>17</sup> DOL, HHS, and Treasury, "FAQS About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation, Part 43," June 23, 2020, at https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf. Hereinafter referred to as Tri-Agency FAQ 43.

<sup>&</sup>lt;sup>18</sup> DOL, HHS, and Treasury, "FAQS About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation, Part 44," February 26, 2021, at https://www.cms.gov/files/document/faqs-part-44.pdf. Hereinafter referred to as Tri-Agency FAQ 44.

<sup>&</sup>lt;sup>19</sup> For a discussion of the agencies' implementation authority and the force of law of these documents, see "Are Plans Required to Cover Testing for Public Health Surveillance or Employment Purposes?" in CRS Report R46481, *COVID-19 Testing: Frequently Asked Questions*.

<sup>&</sup>lt;sup>20</sup> 21 C.F.R. §809.3(a).

<sup>&</sup>lt;sup>21</sup> Although both serology tests and molecular and antigen diagnostic tests meet the regulatory definition of "in vitro diagnostic," applicability to serology testing was not clear based only on the statutory language as it refers to detection and identification of the virus. Serology testing does not detect or identify the virus; rather, it detects antibodies. For more information, see "What Are the Different Types of COVID-19 Tests?" in CRS Report R46481, *COVID-19 Testing: Frequently Asked Questions*.

items and services furnished to an individual during [specified types of visits; discussed below] that result in an order for or administration of [an applicable COVID-19 test; see above], but only to the extent such items and services relate to the furnishing or administration of such product or to the evaluation of such individual for purposes of determining the need of such individual for such product.<sup>22</sup>

Per an example provided in guidance,

if the individual's attending provider determines that other tests (e.g., influenza tests, blood tests, etc.) should be performed during a visit ... to determine the need of such individual for COVID-19 diagnostic testing, and the visit results in an order for, or administration of, COVID-19 diagnostic testing, the plan or issuer must provide coverage for the related tests under section 6001(a) of the FFCRA.<sup>23</sup>

In addition, consumers must not face cost-sharing for "facility fees" or other fees, to the extent they are related to COVID-19 testing or related items and services that are required to be covered under FFCRA Section 6001.<sup>24</sup>

The coverage requirements do not apply to any services or items furnished at a testing visit that are not related to COVID-19 (e.g., if someone received testing or treatment for an unrelated condition at the same visit). In addition, the law and guidance do not explicitly address coverage and cost-sharing for the "related" items and services discussed above if the individual does not ultimately receive the test.<sup>25</sup> The requirements also do not encompass treatment for illnesses associated with COVID-19.<sup>26</sup>

Per FFCRA Section 6001(a)(2), the coverage requirements apply to the specified items and services, discussed above, when furnished at visits including to health care provider offices (including in-person and telehealth visits), urgent care centers, and emergency rooms. Per the Tri-Agency FAQ 42, the requirements also apply at "nontraditional" settings, "including drive-through screening and testing sites where licensed health care providers are administering COVID-19 diagnostic testing."<sup>27</sup>

In addition, guidance indicates that the coverage requirements apply to at-home COVID-19 tests, including at-home swab kits that may be sent to a lab for processing, when such tests are "ordered by an attending health care provider who has determined that the test is medically appropriate for the individual," as specified in guidance.<sup>28</sup>

<sup>&</sup>lt;sup>22</sup> FFCRA §6001(a)(2). Also see the Tri-Agency FAQ 42, including questions five, six, and eight; and Tri-Agency FAQ 44, question five.

<sup>&</sup>lt;sup>23</sup> Tri-Agency FAQ 42, question five.

<sup>&</sup>lt;sup>24</sup> For more information, see the Tri-Agency FAQ 43, question seven, including its footnote 16.

<sup>&</sup>lt;sup>25</sup> Per the Tri-Agency FAQ 42, question five, the coverage of related items and services is required when "the visit results in an order for, or administration of, COVID-19 diagnostic testing." This language also appears in FFCRA Section 6001(a)(2). The statute and guidance do not explicitly address whether the coverage requirements apply if an individual receives the related items and services, even for purposes of determining the need for COVID-19 testing, but does not actually receive a COVID-19 test. Other federal and/or state requirements could be applicable.

<sup>&</sup>lt;sup>26</sup> See "Are Plans Required to Cover COVID-19 Treatment?" in this report for more information.

<sup>&</sup>lt;sup>27</sup> See Tri-Agency FAQ 42, question eight, regarding "nontraditional" visits. Tri-Agency FAQ 44, questions three and four, provide additional details. Also see FAQ 42, question 13, for more information about telehealth visits.

<sup>&</sup>lt;sup>28</sup> Tri-Agency FAQ 43, question four. Also see question three regarding "attending providers."

#### Timing of Requirements and Applicability to Different Types of Plans

The private health insurance coverage requirements in FFCRA apply only to the specified items and services that are furnished during the COVID-19 public health emergency period described in that act, as of the date the FFCRA was enacted (March 18, 2020).<sup>29</sup>

These requirements apply to individual health insurance coverage, fully insured small- and largegroup coverage, and self-insured group plans<sup>30</sup> including grandfathered individual or group plans, which are exempt from certain other federal private health insurance requirements. Per the definition of individual health insurance coverage cited in the act, the requirements do not apply to STLDI.<sup>31</sup>

#### Prohibition of Medical Management Requirements

Following enactment of FFCRA Section 6001, questions arose about the parameters of its testing requirements and its prohibition on "prior authorization or other medical management requirements," including whether plans must pay for testing that is not mainly intended for the clinical or treatment needs of individual patients.<sup>32</sup> These questions centered on whether Section 6001 compels plans to cover testing for other reasons, such as public health surveillance or workplace health purposes. There also have been questions about coverage in general of testing for asymptomatic individuals with no known or suspected recent exposure to COVID-19.

*Medical management* was not defined in statute at the time FFCRA was enacted. However, the Consolidated Appropriations Act, 2021 (P.L. 116-260), enacted in December 2020, contained several references to medical management techniques in its provisions related to surprise billing, such as this parenthetical: "a medical management technique (including concurrent review, prior authorization, and step-therapy or fail-first protocols)."<sup>33</sup> In addition, "reasonable medical management techniques" are referenced in existing federal regulations as techniques that plans may use to "determine the frequency, method, treatment, or setting for an item or service."<sup>34</sup>

<sup>&</sup>lt;sup>29</sup> Some FFCRA and CARES Act coverage requirements are contingent upon the declaration of the COVID-19 public health emergency. This was declared by the HHS Secretary on January 31, 2020, effective as of January 27, pursuant to \$319 of the Public Health Service Act (PHSA). Hence, the emergency period began on January 27, 2020, and remains in effect as long as the declaration, or any renewal of it, is in effect. See "Duration of Emergency Period" in CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*, and HHS, Assistant Secretary for Preparedness and Response, "Public Health Emergency Declarations," at https://www.phe.gov/ emergency/news/healthactions/phe/Pages/default.aspx.

 $<sup>^{30}</sup>$  The requirements technically are applicable to group health plans and health insurers offering individual and group health insurance coverage. In this report, references to *plans* include applicable plans and insurers.

<sup>&</sup>lt;sup>31</sup> See "Background on Private Health Insurance" regarding these types of plans, including grandfathered plans and STLDI.

<sup>&</sup>lt;sup>32</sup> See, for example, Letter from the National Association of Insurance Commissioners (NAIC) and the Center for Insurance Policy and Research, to Alex Azar, HHS Secretary, and Seema Verma, CMS Administrator, at https://www.naic.org/documents/government\_relations\_letter\_to\_azar.pdf.

<sup>&</sup>lt;sup>33</sup> Consolidated Appropriations Act, 2021 (P.L. 116-260), §111 of Division BB, adding §2799A-1(f)(1)(F) to the PHSA. Also see definitions of *medical management systems* ("Systems designed to ensure that members receive appropriate [covered] health care services") and related terms in Box 2-1 and elsewhere in the report: Institute of Medicine (now National Academies of Medicine), *Essential Health Benefits: Balancing Coverage and Cost*, 2012, at https://doi.org/10.17226/13234.

 $<sup>^{34}</sup>$  45 C.F.R. §147.130(a)(4). These regulations address federal requirements on private health insurance coverage of certain preventive services (discussed later in this report).

Although these federal references are informative, their direct relevance to FFCRA Section 6001 is unclear. Administrative guidance has been issued on related questions, however.

The Tri-Agency FAQ 42 interpreted FFCRA Section 6001 as compelling plans to cover testing only "when medically appropriate for the individual, as determined by the individual's attending healthcare provider in accordance with accepted standards of current medical practice."<sup>35</sup> The guidance did not further outline the circumstances in which COVID-19 tests were "medically appropriate"; however, under the agencies' interpretation, the availability of covered testing appeared contingent upon a medical decision by a health care provider responsible for providing care to a specific patient.

The Tri-Agency FAQs 43 and 44 provided additional information. Coverage of testing is required for asymptomatic individuals, whether or not they have had known or suspected recent exposure to SARS-CoV-2.<sup>36</sup> The coverage requirements apply each time an individual receives a diagnostic test for COVID-19, "provided that the tests are diagnostic and medically appropriate for the individual, as determined by an attending health care provider in accordance with current accepted standards of medical practice."<sup>37</sup> FAQ 43 suggests that providers "consult guidance issued by the CDC, as well as state, tribal, territorial, and local health departments or professional societies, when determining whether diagnostic testing is appropriate for a particular individual."<sup>38</sup> FAQ 44 further states,

State and local public health authorities retain the authority to direct providers to limit eligibility for testing based on clinical risk or other criteria to manage testing supplies and access to testing. Responsibility for implementing such state or local limits on testing falks on attending health care providers, not on plans and issuers. Plans and issuers may notuse such criteria to deny (or impose cost sharing on) a claim for COVID-19 diagnostic testing.<sup>39</sup>

However, per FAQ 43, plans are *not* required to cover COVID-19 testing "for general workplace health and safety (such as employee 'return-to-work' programs), for public health surveillance for SARS-CoV-2, or for any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19 or another health condition."<sup>40</sup> This guidance was maintained in FAQ 44, where questions one and two explain that although plans are required to cover testing for *individuals* as explained above (e.g., including for asymptomatic individuals), plans are not similarly required to cover testing for "*groups* of asymptomatic employees or individuals with no known or suspected recent exposure to COVID-19" (emphasis added).

#### Out-of-Network Testing

FFCRA does not specify whether its coverage requirements apply when the test is furnished by an out-of-network provider. However, Section 3202 of the CARES Act addresses insurer payments

<sup>&</sup>lt;sup>35</sup> Tri-Agency FAQ 42, question six.

<sup>&</sup>lt;sup>36</sup> Per Tri-Agency FAQ 43, question five, coverage of testing for asymptomatic individuals was only required if the individuals had known or suspected exposure. This was revised by Tri-Agency FAQ 44, question one, which states that the known or suspected exposure is not required for coverage of individuals' testing.

<sup>&</sup>lt;sup>37</sup> Tri-Agency FAQ 43, question six. Also see question three regarding "attending providers."

<sup>&</sup>lt;sup>38</sup> Ibid.

<sup>&</sup>lt;sup>39</sup> Tri-Agency FAQ 44, question one.

<sup>&</sup>lt;sup>40</sup> Tri-Agency FAQ 43, question five.

to in-network and out-of-network providers. In addition, the Tri-Agency FAQ 42 clarifies that the FFCRA coverage requirements apply both in network and out of network.<sup>41</sup>

For further discussion of coverage and provider reimbursement requirements applicable to out-ofnetwork testing and "balance billing" by out-of-network providers, see "What Coverage and Provider Reimbursement Requirements Apply to Out-of-Network Testing?" and "Are Out-of-Network Providers Allowed to Balance Bill Patients for COVID-19 Testing and Other Related Items and Services?" in CRS Report R46481, *COVID-19 Testing: Frequently Asked Questions*.

#### State and Private-Sector Actions

Both before and after the enactment of FFCRA, some states announced coverage requirements, and some insurers clarified or expanded their policies regarding coverage of COVID-19 testing, among other services.<sup>42</sup> However, states cannot regulate self-insured plans, and insurer announcements do not necessarily apply to those plans. FFCRA does apply to self-insured group plans in addition to the other plan types discussed above.

To the extent that state requirements about or plans' voluntary coverage of COVID-19 testing did not extend as far as FFCRA and CARES Act requirements, the federal laws supersede them. However, state requirements and plans' voluntary coverage may exceed applicable federal requirements, as long as they do not prevent the implementation of any federal requirements.<sup>43</sup>

A state or local department of health or other administrative agency may announce requirements or guidelines regarding testing certain populations or testing for certain public health purposes. However, this does not necessarily mean insurers in that state are required to cover such testing, although that would be the case if the state department of insurance or other relevant agency also requires such coverage or if federal requirements are applicable. This is because it is the state department of insurance, not the state department of health, which regulates insurance. However, see "Prohibition of Medical Management Requirements" regarding Tri-Agency guidance to plans on deferring to providers' implementation of any state and local testing limits.

Even though federal law now requires most plans to cover specified COVID-19 testing services without cost sharing, it may be useful for consumers to contact their insurers or plan sponsors to understand their coverage. Subject to applicable federal and state requirements, coverage of the COVID-19 test and related services and items may vary by plan.

<sup>&</sup>lt;sup>41</sup> Tri-Agency FAQ 42, question seven. Furthermore, question nine of the Tri-Agency FAQ 43 clarifies that out-ofnetwork providers are generally precluded from directly billing a patient for the difference between provider's charge for COVID-19 testing and the amount reimbursed by the health plan (i.e., balance billing). However, a provider is not prevented from balance billing for other items and services unless there is an applicable state law or other prohibition (e.g., pursuant to the terms of the Provider Relief Fund). For background on this funding, see CRS Insight IN11438, *The COVID-19 Health Care Provider Relief Fund*.

<sup>&</sup>lt;sup>42</sup> Several organizations have been tracking these announcements by states and/or insurers. See, for example, the NAIC "Life and Health" resource, updated December 10, 2020, at https://content.naic.org/naic\_coronavirus\_info.htm, and the Association of Health Insurance Plans (AHIP), "Health Insurance Providers Respond to Coronavirus (COVID-19)," updated March 22, 2021, at https://www.ahip.org/health-insurance-providers-respond-to-coronavirus-covid-19/. Note that some of the states' requirements and/or insurers' additional coverage statements have been time-limited and may no longer be in effect. These time limits generally appear to be reflected on the NAIC and AHIP sites.

<sup>&</sup>lt;sup>43</sup> See, for example, the introduction of the Tri-Agency FAQ 42.

### Are Plans Required to Cover COVID-19 Treatment?

#### Essential Health Benefits Guidance on COVID-19 Coverage

Although FFCRA requires certain plans to cover specified COVID-19 *testing* services without cost sharing, neither FFCRA nor the CARES Act mandates coverage of COVID-19 *treatment* services. There is no federal requirement specifically mandating private health insurance coverage of items or services related to COVID-19 treatment. However, one or more existing federal requirements are potentially relevant, subject to state implementation and plan variation.

There is a federal statutory requirement that certain plans cover a core set of 10 categories of *essential health benefits* (EHB).<sup>44</sup> However, states, rather than the federal government, generally specify the benefit coverage requirements within those categories. Current regulation allows each state to select an EHB-benchmark plan. The benchmark plan serves as a reference plan on which plans subject to EHB requirements must substantially base their benefits packages. Because states select their own EHB-benchmark plans, there is considerable variation in EHB coverage from state to state.<sup>45</sup>

On March 5, 2020, and March 12, 2020, CMS issued guidance addressing the potential relevance of EHB requirements to coverage of COVID-19 treatment, among other benefits, subject to variation in states' EHB-benchmark plan designations.<sup>46</sup> According to the March 12 document, "all 51 EHB-benchmark plans currently provide coverage for the diagnosis and *treatment* of COVID-19" (emphasis added), but coverage of specific benefits within the 10 categories of EHB (e.g., hospitalization, laboratory services) may vary by state and by plan.

The March 12, 2020, document suggests that coverage of medically necessary hospitalizations would include coverage of medically necessary isolation and quarantine during the hospital admission, subject to state and plan variation. Quarantine in other settings, such as at home, is not a medical benefit. The document notes, "however, other medical benefits that occur in the home that are required by and under the supervision of a medical provider, such as home health care or telemedicine, may be covered as EHB," subject to state and plan variation.

The March 12, 2020, document confirms that "exact coverage details and cost-sharing amounts for individual services may vary by plan, and some plans may require prior authorization before

<sup>46</sup> Centers for Medicare & Medicaid Services (CMS), "FAQs on Essential Health Benefit Coverage and the Coronavirus (COVID-19)," March 12, 2020, at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/ Downloads/EHB-Benchmark-Coverage-of-COVID-19.pdf. The March 5, 2020, document has similar content: CMS, "Information Related to COVID-19 Individual and Small Group Market Insurance Coverage," at

<sup>&</sup>lt;sup>44</sup> The 10 categories of essential health benefits (EHB) are ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

<sup>&</sup>lt;sup>45</sup> For information about the process for defining the EHB in each state that is in place for plan years beginning before 2020, see CRS Report R44163, *The Patient Protection and Affordable Care Act's Essential Health Benefits (EHB)*. On April 17, 2018, HHS issued a final rule that modifies the process for defining the EHB for plan years beginning in 2020. For more information, see Department of Health and Human Services, "HHS Notice of Benefit and Payment Parameters for 2019," 83 *Federal Register* 16930, April 17, 2018.

https://www.cms.gov/files/document/03052020-individual-small-market-covid-19-fact-sheet.pdf. These fact sheets each also addressed policy considerations related to private health insurance coverage of COVID-19 testing and vaccination. The enactment of FFCRA and the CARES Act have likely superseded much of the information in these documents regarding such coverage of testing and vaccination, but as of the date of this report, the documents are still relevant with regard to coverage of COVID-19 treatment.

these services are covered." In other words, even where certain treatment items and services are required to be covered as EHB in a state, cost-sharing and medical management requirements could apply, subject to applicable federal and state requirements. In addition, cost sharing and other coverage details may vary for services furnished by out-of-network providers.<sup>47</sup>

Individual and fully insured small-group plans are subject to EHB requirements. Large-group plans, self-insured plans, grandfathered plans, and STLDI are not.<sup>48</sup>

Whether or not certain treatment services are defined as EHB in a state, other state benefit coverage requirements may be relevant to COVID-19 treatment. Plans may also voluntarily cover benefits. See "State and Private-Sector Actions," below.

#### Certain Federal Requirements Related to Cost Sharing

Other existing federal requirements are also relevant to consumer cost sharing on COVID-19 treatment services, to the extent that such treatments are covered by the consumer's plan, and largely to the extent that they are defined by a state as EHB.

For example, plans must comply with annual limits on consumers' out-of-pocket spending (i.e., cost sharing, including deductibles, coinsurance, and copayments) on in-network coverage of the EHB.<sup>49</sup> If certain treatment services are defined as EHB in a state, and are furnished by an innetwork provider, consumers' out-of-pocket costs for the plan year would be limited as discussed below. If certain treatment services are not defined as EHB in a state, and/or are furnished by outof-network providers, this out-of-pocket maximum would not necessarily apply.

In 2021, the out-of-pocket limits cannot exceed \$8,550 for self-only coverage and \$17,100 for coverage other than self-only. This means that once a consumer has spent up to that amount in cost sharing on applicable in-network benefits, the plan would cover 100% of remaining applicable costs for the plan year.

The out-of-pocket maximum applies to individual health insurance coverage, fully insured smalland large-group coverage, and self-insured group plans.<sup>50</sup> The requirement does not apply to grandfathered plans or STLDI.

#### State and Private-Sector Actions

As stated above, some states have announced coverage requirements related to COVID-19 testing services and items, and some insurers have clarified or expanded their policies to include relevant coverage.<sup>51</sup> Some of these state and insurer statements also address coverage of treatment

<sup>&</sup>lt;sup>47</sup> However, see CRS Insight IN11438, *The COVID-19 Health Care Provider Relief Fund* regarding the prohibition on Provider Relief Fund recipients from balance billing consumers for "all care for a presumptive or actual case of COVID-19."

<sup>&</sup>lt;sup>48</sup> See "Background on Private Health Insurance" regarding these types of plans, including grandfathered plans and STLDI.

<sup>&</sup>lt;sup>49</sup> 42 U.S.C. §18022. For more information on this requirement, and on other federal cost-sharing requirements that may similarly be relevant (prohibition on lifetime limits and annual limits; minimum actuarial value requirements), see CRS Report R45146, *Federal Requirements on Private Health Insurance Plans*.

<sup>&</sup>lt;sup>50</sup> Certain types of plans—self-insured plans and plans offered in the large-group market—must comply with this requirement even though they are not required to cover the EHB. HHS has indicated that such plans must use a permissible definition of EHB (including any state-selected EHB benchmark plans) to determine whether they comply with the requirement.

<sup>&</sup>lt;sup>51</sup> See footnote 42 regarding organizations that are tracking such activity, and the time-limited nature of some of these

services. However, as discussed above, states cannot regulate self-insured plans, and insurer announcements do not necessarily apply to those plans either.

Coverage, cost sharing, and the application of medical management techniques (e.g., prior authorization) can vary by plan, subject to applicable federal and state requirements. It may be useful for consumers to contact their insurers or plan sponsors to understand their coverage of services and items related to COVID-19 treatment.

### Are Plans Required to Cover COVID-19 Vaccination?

As of the date of this report, three COVID-19 vaccine formulations are available under Emergency Use Authorizations granted by the Food and Drug Administration (FDA) for use in the United States.<sup>52</sup>

For a nationwide vaccination campaign, the federal government has purchased, and is making available to providers at no cost, all COVID-19 vaccines and certain related supplies. There are also relevant federal coverage requirements on plans. This section provides an overview of such federal requirements, including in the context of the federal purchase of all COVID-19 vaccines.

#### **CARES Act and Existing Preventive Services Coverage Requirements**

Prior to the enactment of the CARES Act, there were no federal requirements specifically mandating private health insurance coverage of items or services related to a COVID-19 vaccine.

However, per an existing federal requirement (§2713 of the Public Health Service Act [PHSA]) and its accompanying regulations, most plans must cover specified preventive health services without cost sharing.<sup>53</sup> This includes any preventive service recommended with an Aor B rating by the United States Preventive Services Task Force (USPSTF); or any immunization with a recommendation by the Advisory Committee on Immunization Practices (ACIP), adopted by the Centers for Disease Control and Prevention (CDC), for routine use for a given individual.<sup>54</sup> These coverage requirements apply no sooner than one year after a new or revised recommendation is published.<sup>55</sup>

Requirements of PHSA Section 2713 apply to individual health insurance coverage, fully insured small- and large-group coverage, and self-insured group plans. The requirements do not apply to grandfathered plans or to STLDI. By regulation, plans are generally not required to cover

<sup>54</sup> For further discussion of this provision, see CRS Report R45146, *Federal Requirements on Private Health Insurance Plans.* For more information about the United States Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practice (ACIP), see https://uspreventiveservicestaskforce.org/uspstf/ and https://www.cdc.gov/vaccines/acip/index.html, respectively. For more information about the definition of *routine* use, see Richard Hughes IV, Reed Maxim, and Alessandra Fix, "Vague Vaccine Recommendations May Be Leading To Lack Of Provider Clarity, Confusion Over Coverage," *Health Affairs*, May 7, 2019.

state and/or insurer announcements.

<sup>&</sup>lt;sup>52</sup> See the U.S. Food and Drug Administration (FDA) page, "Emergency Use Authorization," at https://www.fda.gov/ emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-useauthorization#coviddrugs.

<sup>&</sup>lt;sup>53</sup> §2713 was added to the PHSA (codified at 42 U.S.C. §300gg-13) and incorporated into the Employee Retirement Income Security Act (ERISA) and Internal Revenue Code (IRC) by the Patient Protection and Affordable Care Act (ACA; P.L. 111-148, as amended). Regulations are at 45 C.F.R. §147.130; 29 C.F.R. §2590.715-2713; and 26 C.F.R. §54.9815-2713.

<sup>&</sup>lt;sup>55</sup> Per 45 C.F.R. §147.130(b), such coverage is required "for plan years (in the individual market, policy years) that begin on or after the date that is one year after the date the recommendation or guideline is issued."

preventive services furnished out of network. They are allowed to use "reasonable medical management" techniques, within provided guidelines. <sup>56</sup> Cost sharing for office visits associated with a furnished preventive service may or may not be allowed, as specified in regulation. In general, whether cost sharing for office visits is allowed or prohibited depends on whether the preventive service or item was the primary purpose of the visit and whether the service or item was billed or tracked separately from the office visit.<sup>57</sup>

Section 3203 of the CARES Act requires specified plans—the same types as those subject to PHSA Section 2713—to cover COVID-19 vaccines and other COVID-19 preventive services if th recommended by ACIP or USPSTF, respectively.<sup>58</sup> This coverage must be provided without cost sharing. The three vaccines currently authorized for emergency use have been recommended by ACIP.<sup>59</sup>

As compared to existing preventive services coverage requirements, Section 3203 applies an expedited effective date for the required COVID-19 vaccine and preventive services coverage: 15 business days after an applicable ACIP or USPSTF recommendation is published.

CARES Act Section 3203 refers to and largely mirrors PHSA Section 2713 but does not amend it. However, an Interim Final Rule (IFR) published in November 2020 amends applicable preventive services coverage regulations to include CARES Act COVID-19 vaccine coverage requirements, as well as new agency interpretations of such requirements (further discussed below).<sup>60</sup>

The statutory requirements regarding coverage of COVID-19 vaccination and other preventive services are not time limited to the declared COVID-19 public health emergency. The November 2020 IFR's related regulatory amendments expire at the end of the PHE.<sup>61</sup>

#### Private Health Insurance Coverage Given the Federal Purchase of Vaccines

In summer 2020, the federal government announced its purchase of all COVID-19 vaccines, and some related supplies for administration of the vaccine to patients, for purposes of a nationwide pandemic vaccination campaign.<sup>62</sup> It is a federal crime for anyone to sell federally purchased COVID-19 vaccines or receive any inducement for vaccinating (i.e., it is not currently allowable to administer or obtain the vaccine outside of the federal vaccination campaign).<sup>63</sup>

 $<sup>^{56}</sup>$  See 45 C.F.R. 147.130(a)(3) regarding out-of-net work coverage and (a)(4) regarding reasonable medical management.

<sup>&</sup>lt;sup>57</sup> See 45 C.F.R. §147.130(a)(2).

<sup>&</sup>lt;sup>58</sup> Unlike existing preventive services coverage requirements, COVID-19 immunization requirements are applicable regardless of whether an ACIP recommendation is "for routine use." See Tri-Agency FAQ 44, page 5.

<sup>&</sup>lt;sup>59</sup> For discussion of ACIP's COVID-19 vaccine recommendations, see "Clinical Recommendations and Prioritization" in CRS Report R46593, *Vaccine Safety in the United States: Overview and Considerations for COVID-19 Vaccines.* 

<sup>&</sup>lt;sup>60</sup> DOL, HHS and Treasury, "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency," 85 *Federal Register* 71142, November 6, 2020, at https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency. Hereafter referred to as November 2020 IFR.

<sup>&</sup>lt;sup>61</sup> November 2020 IFR, page 71176.

<sup>&</sup>lt;sup>62</sup> See HHS, "U.S. Government Engages Pfizer to Produce Millions of Doses of COVID-19 Vaccine," July 22, 2020, at

https://www.hhs.gov/about/news/2020/07/22/us-government-engages-pfizer-produce-millions-doses-covid-19-vaccine.html. Also see HHS, "Trump Administration Collaborates with Moderna to Produce 100 Million Doses of COVID-19 Investigational Vaccine," August 11, 2020, at https://www.hhs.gov/about/news/2020/08/11/trump-administration-collaborates-with-moderna-produce-100-million-doses-covid-19-investigational-vaccine.html.

<sup>&</sup>lt;sup>63</sup> Centers for Disease Control and Prevention (CDC), "CDC COVID-19 Vaccination Program Provider Requirements

Because the federal government is providing these vaccines and supplies to providers and patients at no cost, plans currently do not need to reimburse providers for these items. However, per the November 2020 IFR, applicable plans still must cover vaccine administration fees (e.g., providers' charges for their time, storage, recordkeeping, and supplies) without consumer cost sharing.<sup>64</sup> Per providers' agreements with the CDC by which they are authorized to participate in the COVID-19 vaccine program, they may bill payers—such as private insurance plans—for such administration fees, but they may not bill patients for them.<sup>65</sup>

It is unclear to some observers whether consumer cost sharing may be possible in certain circumstances, such as an office visit fee for a provider appointment at which administration of the vaccine is not the primary purpose of the visit and depending on how the visit is billed (i.e., the circumstances for which certain cost sharing is allowable under existing preventive services coverage regulations). For office visits involving COVID-19 vaccination, the November IFR prohibits consumer cost sharing in the same circumstances for which it is prohibited under existing preventive services coverage provisions. It is silent on whether cost sharing is conversely allowable for office visits involving COVID-19 vaccination, when it is allowable for other preventive services. No other potential fees (e.g., *facility fees*) are addressed in statute or guidance, and the CDC rules on provider billing related to the vaccine also are silent on fees other than a vaccine administration fee.

#### Out-of-Network Coverage

CARES Act Section 3202 does not address out-of-network coverage of the vaccine or related costs but states that such coverage shall be "pursuant to PHSA Section 2713 and related regulations." PHSA Section 2713 coverage requirements generally do not apply out of network.

The November 2020 IFR, however, amends the relevant regulations to require COVID-19 vaccines and preventive services coverage without cost sharing, regardless of whether they are provided in network or out of network.<sup>66</sup> The IFR includes requirements for plans' reimbursement of out-of-network providers to be "reasonable, as determined in comparison to prevailing market rates for such service." These additional requirements apply only during the PHE period, however; beyond the PHE period, the coverage requirements still apply in network.

#### State and Private-Sector Actions

Some of the state and insurer announcements about coverage of COVID-19 benefits, discussed earlier in this report, reference vaccine coverage.<sup>67</sup> Even though the federal purchase of vaccines is in effect across the U.S., consumers may still find it useful to contact their insurers or plan sponsors to understand their coverage of services and items related to the administration of the vaccine.

and Support," updated January 7, 2021, at https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html. <sup>64</sup> November 2020 IFR, beginning on page 71174.

<sup>&</sup>lt;sup>65</sup> See CRS Insight IN11609, COVID-19 Vaccine: Financing for Its Administration.

<sup>&</sup>lt;sup>66</sup> November IFR, page 71175.

<sup>&</sup>lt;sup>67</sup> See footnote 42. Besides the AHIP resource listed earlier, the organization nowalso has a list of insurer announcements specific to COVID-19 vaccines: https://www.ahip.org/ensuring-access-to-covid-19-vaccines/.

## Appendix. Resources for Questions About Private Health Insurance and COVID-19-Related Services

This report has focused on coverage of COVID-19 testing, treatment, and vaccination by most types of private health insurance plans. CRS analysts are also available to congressional clients to discuss other topics of interest related to private health insurance and COVID-19, including

- coverage of COVID-19 benefits by types of private plans not specifically addressed in this report;
- other issues related to private coverage of COVID-19 benefits;
- private coverage of certain other benefits of concern during this pandemic, or of services furnished via telehealth; and
- issues related to private health insurance enrollment and premium payments.

The following table lists examples of such topics of interest, any relevant legislative or administrative resources, any relevant CRS resources, and names of appropriate CRS experts for the benefit of congressional clients. Besides the CRS reports listed below that provide background on relevant topics, also see CRS reports on health provisions in recent COVID-19 legislation and a CRS report that provides more detail on COVID-19 testing issues, including private health insurance coverage:

- CRS Report R46316, Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127
- CRS Report R46334, Selected Health Provisions in Title III of the CARES Act (P.L. 116-136)
- CRS Report R46481, COVID-19 Testing: Frequently Asked Questions
- CRS Insight IN11609, COVID-19 Vaccine: Financing for Its Administration

The information in this report is current as of its publication date and may be superseded by subsequent congressional or administrative action. Congressional clients may contact the report author and/or experts listed below for questions about further developments. In addition, CMS guidance related to private health insurance and COVID-19 is compiled on its website.<sup>68</sup>

<sup>&</sup>lt;sup>68</sup> CMS, CCIIO, "Coronavirus Disease 2019 (COVID-19) Guidance," accessed February 17, 2021, at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs#COVID-19.

#### Table A-I. Resources for Further Questions About Private Health Insurance

|  | Key Federal Resources  | <b>CRS</b> Resources  | <b>CRS</b> Experts  |  |
|--|--|---|---|--|
| Coverage of COVID-   | 19 benefits by types of pri  | vate plans not addressed in this repo   | rt  |  |
| Federal Employees<br>Health Benefits<br>(FEHB) Program                                     | FFCRA §6006  | CRS Report R43922, Federal<br>Employees Health Benefits (FEHB)<br>Program: An Overview  | Noah Isserman   |  |
| Catastrophic plans   | CMS March 18 FAQ <sup>a</sup>  | CRS Report R44065, Overview of<br>Health Insurance Exchanges  | Vanessa<br>Forsberg                                       |  |
| Certain other health<br>coverage<br>arrangements <sup>b</sup>                              | Tri-Agency FAQ 42°<br>Tri-Agency FAQ 43 <sup>d</sup><br>Tri-Agency FAQ 44°   | CRS Report R46003, Applicability of<br>Federal Requirements to Selected Health<br>Coverage Arrangements   | Vanessa<br>Forsberg                                       |  |
| Other issues related   | to private coverage of CO  | VID-19 benefits   |   |  |
| Health savings account<br>(HSA) eligibility and<br>high-deductible health<br>plans (HDHPs) | IRS March 11 Notice <sup>f</sup><br>CARES Act §3701 and<br>§3702   | CRS Report R45277, Health Savings<br>Accounts (HSAs)  | Ryan Rosso  |  |
| Out-of-network<br>coverage and surprise<br>billing   | Tri-Agency FAQ 42 <sup>c</sup><br>Tri-Agency FAQ 43 <sup>d</sup><br>Tri-Agency FAQ 44 <sup>e</sup><br>HHS Provider Relief<br>Funding Terms and<br>Conditions <sup>g</sup><br>CARES Act §3202 | CRS Report R46116, Surprise Billing in<br>Private Health Insurance: Overview and<br>Federal Policy Considerations   | Ryan Rosso<br>Noah Isserman                               |  |
| Private coverage of c  | ertain benefits not addres   | sed in this report  |   |  |
| Mental health  | Tri-Agency FAQ 43 <sup>d</sup>   | N/A   | Noah Isserman<br>(coverage)<br>Johnathan Duff             |  |
| Telehealth   | CMS March 24 Telehealth<br>FAQ <sup>h</sup><br>Tri-Agency FAQ 42 <sup>c</sup>  | CRS Report R46239, Telehealth and<br>Telemedicine: Frequently Asked Questions   | (service provision)<br><b>Noah Isserman</b><br>(coverage) |  |
| Prescription drugs   | Tri-Agency FAQ 43 <sup>d</sup><br>CMS March 24<br>Prescription Drug FAQ <sup>i</sup>   | Consumer out-of-pocket drug costs<br>section of CRS Report R44832,  | Elayne Heisler<br>(service provision)<br>Noah Isserman    |  |
|  |  | Frequently Asked Questions About<br>Prescription Drug Pricing and Policy  |   |  |
|  | nce enrollment and premi   | ums   | Managa  |  |
| Health insurance<br>exchanges  | Healthcare.gov COVID-<br>19 page <sup>j</sup>  | CRS Report R44065, Overview of<br>Health Insurance Exchanges  | Vanessa<br>Forsberg                                       |  |
| Premium payments;<br>premium tax credits<br>and cost-sharing<br>subsidies                  | CMS March 24 Premium<br>Payment FAQ <sup>k</sup><br>CMS August 4 Premium<br>Credit Guidance <sup>l</sup>   | CRS Report R44425, Health Insurance<br>Premium Tax Credits and Cost-Sharing<br>Subsidies<br>CRS Report R44392, The Health<br>Coverage Tax Credit (HCTC): In Brief | Bernadette<br>Fernandez                                   |  |

FFCRA and CARES Act provisions are discussed in the reports listed in the Appendix

|                                       | Key Federal Resources | <b>CRS Resources</b>  | CRS Experts |
|---------------------------------------|-----------------------|---|-------------|
| Loss of employment-<br>based coverage | N/A                   | CRS In Focus IFI I 523, Health<br>Insurance Options Following Loss of<br>Employment | Ryan Rosso  |
|                                       |                       | CRS Report R40142, Health Insurance<br>Continuation Coverage Under COBRA            |             |

#### Source: Created by CRS.

**Notes:** This table is not meant to represent a comprehensive list of topics related to private health insurance coverage and COVID-19. "FFCRA" is the Families First Coronavirus Response Act. "CARES Act" is the Coronavirus Aid, Relief, and Economic Security Act. "CMS" is the Centers for Medicare & Medicaid Services. "IRS" is the Internal Revenue Service. "Tri-Agency" refers to the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury.

- a. CMS, "FAQs on Catastrophic Plan Coverage and the Coronavirus Disease 2019 (COVID-19)," March 18, 2020, at https://www.cms.gov/CCIIO/Resources/Files/Catastrophic-Coverage-of-COVID-19.pdf.
- b. The Tri-Agency FAQ 42 notes the applicability of FFCRA requirements to certain types of plans not addressed in this report, including nonfederal governmental plans, church plans, student plans, group health plans covering fewer than two current employees (including "retiree plans"), and plans in their provision of excepted benefits. It also addresses short-term, limited-duration insurance (STLDI). Background on some of these coverage arrangements is provided in the CRS report noted above.
- c. DOL, HHS, and Treasury, "FAQS About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation, Part 42," April 11, 2020, at https://www.cms.gov/files/ document/FFCRA-Part-42-FAQs.pdf.
- d. DOL, HHS, and Treasury, "FAQS About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation, Part 43," June 23, 2020, at https://www.cms.gov/files/ document/FFCRA-Part-43-FAQs.pdf.
- e. DOL, HHS, and Treasury, "FAQS About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation, Part 44," February 26, 2021, at https://www.cms.gov/ files/document/faqs-part-44.pdf.
- f. IRS, "HIGH DEDUCTIBLE HEALTH PLANS AND EXPENSES RELATED TO COVID-19," March 11, 2020, at https://www.irs.gov/pub/irs-drop/n-20-15.pdf.
- g. HHS, "Acceptance of Terms and Conditions," February 25, 2021, at https://www.hhs.gov/sites/default/files/ relief-fund-payment-terms-and-conditions.pdf.
- h. CMS, "FAQs on Availability and Usage of Telehealth Services through Private Health Insurance Coverage in Response to Coronavirus Disease 2019," March 24, 2020, at https://www.cms.gov/files/document/faqs-telehealth-covid-19.pdf.
- i. CMS, "FAQs on Prescription Drugs and the Coronavirus Disease 2019 (COVID-19) for Issuers Offering Health Insurance Coverage in the Individual and Small Group Markets," March 24, 2020, at https://www.cms.gov/files/document/faqs-rx-covid-19.pdf.
- j. Healthcare.gov, "Marketplace Coverage & Coronavirus," accessed February 25, 2020, at https://www.healthcare.gov/coronavirus/. In addition, some organizations are tracking state-based exchanges' decisions to open special enrollment periods. For example, see National Association of Insurance Commissioners (NAIC), "State Bulletins and Alerts," "Life and Health Chart," updated December 10, 2020, at https://content.naic.org/naic\_coronavirus\_info.htm.
- k. CMS, "Payment and Grace Period Flexibilities Associated with the COVID-19 National Emergency," March 24, 2020, at https://www.cms.gov/files/document/faqs-payment-and-grace-period-covid-19.pdf.
- I. CMS, "Temporary Policy on 2020 Premium Credits Associated with the COVID-19 Public Health Emergency," August 4, 2020, at https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Premium-Credit-Guidance.pdf.

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