

March 27, 2020

## Key Provisions of the “Phase Three” COVID-19 Stimulus Package

On March 25, 2020, the Senate passed the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act” or the “Act”), an emergency stimulus package that aims to provide financial assistance and other relief to individual taxpayers, businesses, and certain industries that have been particularly affected by the ongoing novel coronavirus (“COVID-19”) pandemic.<sup>1</sup> The House expects to approve the bill today. The President has indicated that he plans to sign the bill immediately.<sup>2</sup> The CARES Act is the third piece of legislation—“phase three”—that Congress has fast-tracked to combat the financial and public health impact of COVID-19.<sup>3</sup>

This Memorandum provides a short executive summary, followed by more detailed summaries of key provisions of the approximately 900-page CARES Act, including its provisions for loans and other relief for small businesses, emergency funding for companies that have suffered severe financial consequences as a result of COVID-19, financial assistance and other benefits—such as the expansion of unemployment benefits—to individual taxpayers, and increased measures to support the healthcare response to COVID-19. For additional resources and real-time updates regarding new legal developments in connection with COVID-19, please visit Paul, Weiss’s [Coronavirus Resource Center](#).

### I. Executive Summary

#### Loans and Other Relief for Small Businesses and Other Organizations

The CARES Act appropriates \$349 billion in additional funds for guaranteed loans under the Small Business Administration’s (“SBA”) section 7(a) loan program and expands the scope of the program to assist small businesses during the COVID-19 emergency.<sup>4</sup> The Act enhances access to section 7(a) loans by relaxing loan eligibility criteria for certain small businesses and organizations, increasing the limit on loan and guarantee amounts, expanding the allowable uses of the proceeds of the loans, and allowing certain other non-SBA entities to lend funds under the program.<sup>5</sup> Additionally, the Act provides entrepreneurial grants to help small businesses, particularly women- and minority-owned small businesses, that have been

<sup>1</sup> Coronavirus Aid, Relief, and Economic Security Act, H.R. 748, 116th Cong. (2020). All citations are to the Senate bill.

<sup>2</sup> Philip Ewing & Barbara Sprunt, *President Trump Urges Swift Passage Of Coronavirus Relief Bill*, NPR (March 25, 2020), <https://www.npr.org/2020/03/25/819125708/watch-white-house-to-hold-coronavirus-briefing-amid-stimulus-bill-uncertainty>.

<sup>3</sup> Congress’s Phase I legislation in response to COVID-19—the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020—was enacted on March 6, 2020. Its Phase II legislation—the Families First Coronavirus Response Act—was enacted on March 18, 2020. See Paul, Weiss Client Memorandum, “Congress Passes COVID-19 Relief Package” (Mar. 18, 2020), available [here](#).

<sup>4</sup> H.R. 748, §§ 1102, 1107.

<sup>5</sup> *Id.* § 1102.

affected by the COVID-19 emergency.<sup>6</sup> It also expands access to the SBA's Economic Injury Development Loans, and provides bankruptcy protections to certain debtors.<sup>7</sup>

### **Financial Assistance for Certain Affected Industries and Other Companies**

The CARES Act appropriates up to \$500 billion in funding for loans, loan guarantees, and investments to provide liquidity to eligible businesses that are suffering as a direct result of the COVID-19 pandemic, including commercial airlines, air cargo companies, and businesses critical to maintaining national security.<sup>8</sup> \$454 billion of this total is available to businesses outside of the aforementioned industries who do not otherwise have access to credit. Recipients of funds will be subject to certain restrictions, such as being unable to repurchase any outstanding equity interests or extend any dividends while a loan is outstanding.<sup>9</sup> Additionally, certain recipients of loans and guarantees must agree that employees paid \$425,000 per year or more will not receive an increase in pay until at least one year after the loan is fully repaid.<sup>10</sup>

The extension of these loans and investments will be monitored by a newly-created Special Inspector General's office and through a Congressional Oversight Commission.<sup>11</sup> The Act also provides stability to the banking system by granting the Federal Deposit Insurance Corporation ("FDIC") additional authority to establish debt guarantee programs and adjust the capital leverage ratio for community banks.<sup>12</sup> It further relaxes several accounting standards currently in place for financial institutions, as related to the categorization of "troubled debt restructuring" and the classification of current expected credit losses.<sup>13</sup>

### **Health Care Response to COVID-19**

The CARES Act contains a number of provisions meant to increase production and accessibility to resources to combat the spread of COVID-19.<sup>14</sup> These provisions include addressing and preventing a shortage of medical supplies and devices necessary for the treatment, prevention, and diagnosis of COVID-19. The Act also includes provisions designed to increase access to health care services, including by amending and extending the Families First Coronavirus Response Act's ("FFCRA") no-cost COVID-19 testing

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<sup>6</sup> *Id.* §§ 1103, 1108.

<sup>7</sup> *Id.* §§ 1110, 1113.

<sup>8</sup> *Id.* § 4003(b).

<sup>9</sup> *Id.* § 4003(c).

<sup>10</sup> *Id.* § 4004.

<sup>11</sup> *Id.* §§ 4018, 4020.

<sup>12</sup> *Id.* §§ 4008, 4012.

<sup>13</sup> *Id.* §§ 4013, 4014.

<sup>14</sup> *Id.* §§ 3001–3121.

requirements with respect to group health plans and insurance issuers offering group or individual health insurance.<sup>15</sup>

### **Financial Assistance for Individual Taxpayers**

The CARES Act provides financial assistance to individuals through tax rebates, expanded unemployment insurance benefits, and modifications to rules governing retirement accounts, retirement plans, and charitable contributions.

## **II. Loans and Other Relief for Small Businesses and Other Organizations**

### **Small Business “Paycheck Protection Program”**

#### *Eligibility*

The section 7(a) loan program is the SBA’s primary method for providing financial assistance to small businesses. The CARES Act expands section 7(a) loan eligibility through June 30, 2020 through a new Paycheck Protection Program, to include the following:

- (i) any business concern, nonprofit organization, veterans organization, or Tribal business concern that employs not more than the greater of 500 employees or the number of employees established by the SBA for the industry in which the entity operates;
- (ii) individuals who operate as sole proprietorships or independent contractors, or are self-employed; and
- (iii) businesses in the accommodation and food services industry with no more than 500 employees per location.<sup>16</sup>

Although the Paycheck Protection Program includes a limit on the size of eligible businesses, it waives certain affiliation rules for: (i) businesses operating as a franchise; (ii) businesses in the accommodation and food services sectors with no more than 500 employees; and (iii) businesses that receive financial assistance from a licensed small business investment company.<sup>17</sup> The bill does not otherwise waive existing SBA affiliate rules, which generally aggregate the employees of companies that are under common control.<sup>18</sup>

<sup>15</sup> See Paul, Weiss Client Memorandum, “Congress Passes COVID-19 Relief Package” (Mar. 18, 2020), available [here](#).

<sup>16</sup> *Id.* § 1102(a)(2).

<sup>17</sup> *Id.*

<sup>18</sup> See 13 CFR § 121.103.

For purposes of calculating whether an entity employs not more than 500 employees, employers are required to count each individual employed on a full-time, part-time, or other basis.<sup>19</sup>

Borrowers must certify: (i) that the current economic uncertainty makes the loan necessary to support ongoing operations; and (ii) that the loan proceeds will be used to retain workers and maintain payroll or make mortgage, rent, and utility payments.<sup>20</sup>

The Act waives the SBA's standard requirement that section 7(a) loan applicants be "unable to obtain credit elsewhere."<sup>21</sup> Applicants that have received an SBA Economic Injury Disaster Loan (another type of loan offered by the SBA outside of the section 7(a) loan program) after January 31, 2020 may still apply for section 7(a) loans, but may not use the proceeds for the same purpose.<sup>22</sup>

#### *Loan Amounts, Terms, and Uses*

The Paycheck Protection Program authorizes loans in amounts up to the lesser of:

- i) \$10 million (which replaces the existing section 7(a) cap of \$5 million); Or
- ii) 2.5 times the recipient's average monthly payroll costs<sup>23</sup> during the one-year period before the loan is made,<sup>24</sup> plus the value of any outstanding SBA disaster loan received after January 31, 2020, for purposes of refinancing the disaster loan.<sup>25</sup>

These loans will have a maximum interest rate of 4% with all lender fees, as well as collateral and personal guarantee requirements waived,<sup>26</sup> and be 100% guaranteed by the SBA.<sup>27</sup> Lenders are required to defer payments of principal, interest, and fees on these loans for between six months and one year, with the SBA to issue deferment guidance to lenders within 30 days of enactment.<sup>28</sup>

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<sup>19</sup> H.R. 748, § 1102(a)(2).

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> The Paycheck Protection Program includes a detailed definition of "payroll costs" which excludes, among other things, compensation for any individual employee earning in excess of \$100,000 in annual salary, as prorated for the period from February 15 to June 30, 2020 and compensation for employees residing outside the United States. *Id.*

<sup>24</sup> For seasonal employers: the average total monthly payroll costs for the business during the 12-week period beginning February 15, 2019 or, at the election of the business, March 1, 2019. *Id.* For businesses not in operation between February 15, 2019 and June 30, 2019: the average total monthly payroll costs for the business between January 1, 2020 and February 29, 2020. *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> *Id.* § 1102(a)(1)(B).

<sup>28</sup> *Id.* § 1102(a)(2).

Businesses may use the borrowed funds not only for standard section 7(a) purposes,<sup>29</sup> but also for payroll costs; insurance premiums; costs related to the continuation of healthcare benefits during paid sick, medical, or family leave; employee salaries, commissions, or similar compensations; utility, rent, and mortgage interest payments; and interest on debt obligations incurred before February 15, 2020.<sup>30</sup>

The Act appropriates \$349 billion to the SBA for the cost of guaranteed loans under the Paycheck Protection Program.<sup>31</sup>

### *Loan Forgiveness*

The portion of the loan used to cover payroll (not including the compensation for any individual employee above \$100,000 on an annual basis, prorated), mortgage interest, rent, or utility costs for the eight-week period beginning on the date the loan is granted is eligible for forgiveness, with the forgiven amount nontaxable.<sup>32</sup> This amounts to a giveaway of money by the government to small businesses—the forgiven amount of the loan is considered canceled debt<sup>33</sup> and is excluded from gross income for federal tax purposes.<sup>34</sup>

In order to incentivize the retention of employees at existing salaries, the amount of forgiveness is reduced by:

- i) any reduction in the average number of monthly full-time equivalent (“FTE”) employees during the eight weeks following loan disbursement as compared to the average number of monthly FTE employees during, at the recipient’s election, either the period between February 15 and June 30, 2019 or the period between January 1 and February 29, 2020, with special rules for seasonal employers; and
- ii) the amount of any reduction in total salary or wages of any employee during the eight weeks following loan disbursement that is in excess of 25% of that employee’s total salary or wages during their most recent full quarter of employment (excluding employees who received,

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<sup>29</sup> Traditionally, the proceeds from section 7(a) loans may be used in most instances only for “plant acquisition, construction, conversion, or expansion, including the acquisition of land, material, supplies, equipment, and working capital.” 15 U.S.C. § 636(a).

<sup>30</sup> H.R. 748, § 1102(a)(2).

<sup>31</sup> *Id.* § 1107(a)(1).

<sup>32</sup> *Id.* § 1106(b).

<sup>33</sup> *Id.* § 1106(c).

<sup>34</sup> *Id.* § 1106(i).

during any single pay period in 2019, wages or salary at an annualized rate of pay of more than \$100,000).<sup>35</sup>

To encourage businesses to rehire employees and reverse recent salary reductions, these loan forgiveness reductions, with respect to any layoffs or salary cuts made between February 15, 2020 and 30 days after enactment of the Act, will not be applied if the business increases its FTEs and employee salaries by June 30, 2020 to the levels in effect on February 15, 2020.<sup>36</sup> Borrowers with tipped employees may receive forgiveness for additional wages paid to them.<sup>37</sup>

There are detailed application and documentation requirements for borrowers seeking loan forgiveness, with forgiveness capped at the amount of the loan principal.<sup>38</sup>

#### *Relief for Existing SBA Section 7(a) Borrowers*

The CARES Act also directs the SBA to pay the principal, interest, and associated fees due on all section 7(a) loans that were granted before the date of enactment of the Act, and that are in regular servicing status, for the six-month period beginning on the date that the next payment is due.<sup>39</sup> For section 7(a) loans (other than Paycheck Protection Loans created under this Act) that are granted during the first six months after its enactment, the SBA will make these payments for the six-month period beginning on the date the first payment is due.<sup>40</sup> The Act appropriates \$17 billion to the SBA for these payments.<sup>41</sup>

For further discussion of modifications to the section 7(a) loan program, please see Paul, Weiss Client Memorandum, “CARES Act to Expand Access to the SBA Loan Program” (Mar. 26, 2020), available [here](#).

#### **Expansion of the SBA’s Economic Injury Disaster Loan Program**

The CARES Act also expands the SBA’s Economic Injury Disaster Loan (“EIDL”) program by relaxing eligibility criteria and increasing funding for EIDL loans through December 31, 2020.<sup>42</sup>

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<sup>35</sup> *Id.* § 1106(d).

<sup>36</sup> *Id.*

<sup>37</sup> *Id.* § 1106(d)(4).

<sup>38</sup> *Id.* § 1106(d)(1).

<sup>39</sup> *Id.* § 1112(c)(1)(A). For such loans in deferment, the SBA shall make all such payments during the six-month period beginning on the date that the next payment is due after the deferment period ends. *Id.* § 1112(c)(1)(B).

<sup>40</sup> *Id.* § 1112(a), (c)(1)(C).

<sup>41</sup> *Id.* § 1112(f).

<sup>42</sup> *Id.* § 1110.

### *Eligibility*

The Act provides that, in addition to small business concerns, private nonprofit organizations, and agricultural cooperatives traditionally eligible for EIDLs, individuals operating under a sole proprietorship or as an independent contractor, and businesses, cooperatives, employee stock ownership plans (“ESOPs”), or tribal small business concerns with not more than 500 employees are eligible to apply for EIDLs through December 31, 2020.<sup>43</sup> Businesses must have been in operation on January 31, 2020 to be eligible.<sup>44</sup>

During the operative period, there will be no personal guarantee requirement on all loans up to \$200,000, no requirement that applicants be in business for one year prior to the COVID-19 disaster, and no requirement that applicants be “unable to obtain credit elsewhere” to be eligible for EIDLs.<sup>45</sup> The SBA may approve applicants during this period based solely on their credit score or on “alternative appropriate methods” of determining their ability to repay.<sup>46</sup>

### *EIDL Emergency Grant Advances*

Any EIDL applicant during this period may also request that the SBA provide an advance of the requested loan, up to \$10,000, within three days of the SBA’s receipt of the applicant’s application.<sup>47</sup> In addition to traditionally allowable EIDL purposes, proceeds from these advances can be used to provide COVID-19-related paid sick leave, maintain payroll to retain employees during business disruptions or slowdowns, pay increased costs due to interrupted supply chains, make rent or mortgage payments, and repay obligations that cannot be met due to revenue losses.<sup>48</sup> Applicants are not required to repay any portion of this advance, even if they are ultimately denied a loan.<sup>49</sup> If an EIDL applicant receives an advance and transfers into or is approved for a SBA section 7(a) loan, the advance will be reduced from the loan forgiveness amount.<sup>50</sup> The Act appropriates \$10 billion to the SBA for these EIDL emergency advances.<sup>51</sup>

### **Small Business Bankruptcy Protections**

The CARES Act also modifies the bankruptcy code to provide certain relief to debtors.<sup>52</sup> The Act raises the eligibility limit for small business debtor reorganization for debtors engaged in commercial or business activities—including any affiliate that is also a debtor—from \$2.7 million to \$7.5 million in aggregate

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<sup>43</sup> *Id.* § 1110(a) & (b).

<sup>44</sup> *Id.* § 1110(c)(2).

<sup>45</sup> *Id.* § 1110(c).

<sup>46</sup> *Id.* § 1110(d).

<sup>47</sup> *Id.* § 1110(e)(1), (3).

<sup>48</sup> *Id.* § 1110(e)(4).

<sup>49</sup> *Id.* § 1110(e)(5).

<sup>50</sup> *Id.* § 1110(e)(6).

<sup>51</sup> *Id.* § 1110(e)(7).

<sup>52</sup> *Id.* § 1113.

noncontingent liquidated secured and unsecured debts, if at least 50% of those debts arose from the debtor's commercial or business activities.<sup>53</sup> Debtors that are corporations subject to reporting requirements under sections 3 or 15(d) of the Securities Exchange Act of 1934<sup>54</sup> or that are affiliates of an issuer, as defined in section 3 of the 1934 Act,<sup>55</sup> generally do not qualify for small business debtor reorganization.<sup>56</sup>

The Act also revises the bankruptcy code to clarify that payments made under federal law relating to the COVID-19 emergency shall be excluded from definitions of current monthly income and disposable income.<sup>57</sup> Additionally, Chapter 13 reorganization plans confirmed before the enactment of this Act may be modified upon the request of such a debtor who "has experienced a material financial hardship due" to the COVID-19 emergency.<sup>58</sup> These forms of relief will be in effect for one year after the date of enactment of the CARES Act.<sup>59</sup>

### **III. Financial Assistance for Certain Affected Industries and Other Companies**

#### **Coronavirus Economic Stabilization Act of 2020**

The CARES Act includes the Coronavirus Economic Stabilization Act of 2020 (the "CESA"), which appropriates \$500 billion dollars and enacts other measures to provide liquidity to eligible businesses that are suffering as a direct result of the COVID-19 emergency.<sup>60</sup>

#### *Direct Loans, Loan Guarantees, and Investments in Credit Facilities to Provide Liquidity*

The CESA authorizes the U.S. Department of the Treasury (the "Treasury") to provide up to \$25 billion in loans or loan guarantees to commercial airlines, ticket agents, and businesses that perform aircraft maintenance inspection services, \$4 billion in loans or loan guarantees to cargo air carriers, and \$17 billion in loans and loan guarantees to businesses critical to maintaining national security.<sup>61</sup> Treasury is also authorized to provide \$454 billion (plus any amount of funding that is not provided to the airline or national security industries) in loans, loan guarantees and other investments to support credit facilities established by the Federal Reserve that will provide liquidity to the financial system and facilitate lending to eligible businesses, states, or municipalities.<sup>62</sup> The credit facilities established by the Federal Reserve are permitted

<sup>53</sup> *Id.* § 1113(a)(1).

<sup>54</sup> 15 U.S.C. §§ 78m, 78o(d).

<sup>55</sup> *Id.* § 78(c).

<sup>56</sup> H.R. 748, § 1113(a)(1).

<sup>57</sup> *Id.* § 1113(b)(1)(A)–(B).

<sup>58</sup> *Id.* § 1113(b)(1)(C).

<sup>59</sup> *Id.* § 1113(b).

<sup>60</sup> *Id.* § 4003(a).

<sup>61</sup> *Id.* § 4003(b)(1)–(3).

<sup>62</sup> *Id.* § 4003(b)(4).

to purchase corporate, state, and municipal bonds either directly from the issuer or in the secondary market, or make direct loans to eligible businesses.<sup>63</sup> A business is eligible to receive financial support under the CESA if it is created or organized under the laws of the United States, and has “significant operations” and a majority of its employees based in the United States.<sup>64</sup>

The CESA provides that Treasury and the Federal Reserve should endeavor to create a program or facility that provides special assistance to U.S.-based mid-size businesses and non-profit organizations with between 500 and 10,000 employees.<sup>65</sup> This program or facility should provide financing to banks and other lenders that make direct loans to mid-size businesses with an interest rate no greater than two percent, and have no principal or interest amount payable within the first six months after a loan is made.<sup>66</sup> Mid-size businesses who receive these loans are required to make a good-faith certification that, among other things, the uncertainty of the current economic environment makes the loan necessary to maintain its ongoing operations, that it will use the funds to retain at least 90% of its workforce at full compensation until September 30, 2020, and it will not outsource or offshore jobs until two years after completing repayment of the loan.<sup>67</sup>

Treasury has discretion as to the form, terms and conditions, covenants, and requirements of the loans, guarantees, and investments.<sup>68</sup> Recipients of any loans or guarantees under the CESA are prohibited from repurchasing any outstanding equity interests until one year after the loan is no longer outstanding, except to the extent required under a pre-existing contractual obligation.<sup>69</sup> Recipients are also not permitted to pay dividends on any outstanding common stock until one year after the loan or loan guarantee is fully repaid.<sup>70</sup> These loans, guarantees, and investments may be made by Treasury until December 31, 2020.<sup>71</sup> Loans made under the CESA may not be forgiven.<sup>72</sup>

Treasury is authorized to provide the aforementioned loans and guarantees to eligible aviation and national security businesses if it determines that: (i) credit is not reasonably available; (ii) the intended obligation is “prudently incurred”; and (iii) the loan is “sufficiently secured” or is made at an interest rate that reflects the risk of the loan.<sup>73</sup> To receive a loan or guarantee, the company must have incurred, or expect to incur, business losses related to the coronavirus pandemic that would jeopardize its continued operations.<sup>74</sup>

<sup>63</sup> *Id.* §§ 4003(b)(4), 4003(c)(3)(E).

<sup>64</sup> *Id.* § 4003(c)(3)(C).

<sup>65</sup> *Id.* § 4003(c)(3)(D).

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> *Id.* § 4003(c)(2).

<sup>69</sup> *Id.* § 4003(c)(2)(E).

<sup>70</sup> *Id.* § 4003(c)(2)(F).

<sup>71</sup> *Id.* § 4029.

<sup>72</sup> *Id.* § 4003(d)(3).

<sup>73</sup> *Id.* § 4003(c)(2).

<sup>74</sup> *Id.*

Recipients of these loans and guarantees are required, to the extent practicable, to maintain existing employment levels until September 30, 2020, and cannot reduce its employment levels by more than 10 percent.<sup>75</sup> Treasury must also enter into contracts with loan recipients to ensure that the federal government receives equity interests, warrants, or senior debt instruments of the loan recipient.<sup>76</sup> These loans and guarantees may not exceed five years.<sup>77</sup>

To receive a loan or guarantee, businesses must enter into a legally binding agreement with Treasury under which, until one year after the loan or guarantee is no longer outstanding, no officer or employee whose total compensation exceeded \$425,000 in calendar year 2019 will receive: (i) total compensation during any twelve-month period that exceeds the officer's or employee's 2019 total compensation; or (ii) termination or severance benefits which exceeds twice the maximum of the officer's or employee's 2019 total compensation.<sup>78</sup> For officers or employees whose total compensation exceeds \$3 million, compensation will be capped at the sum of: (i) \$3 million and (ii) 50% of the excess over \$3 million that the officer or employee received in 2019.<sup>79</sup> The CESA also authorizes the U.S. Department of Transportation ("DOT") to require any airline receiving loans or guarantees to maintain certain scheduled air transportation services as deemed necessary by the DOT.<sup>80</sup> It also suspends certain excise taxes related to air travel from the date the CARES Act is enacted until December 31, 2020.<sup>81</sup>

The CESA also has a "conflict of interest" provision, which prohibits a business from receiving funding under the Act when at least 20% of its outstanding stock is owned by the President, Vice President, an Executive Department head, a member of Congress, or any such individual's immediate family member.<sup>82</sup>

### *Oversight of Distribution of Funds*

The loans, guarantees and investments made under the CESA will be monitored by a newly-created Special Inspector General for Pandemic Recovery.<sup>83</sup> The Special Inspector General will have the authority to conduct investigations and audits related to the making, purchase, management and sale of any loans, guarantees, or investments made by Treasury.<sup>84</sup> The Special Inspector General is required to keep Congress informed through quarterly reports that provide the details of all loans, guarantees, and other investments that have been made.<sup>85</sup> Similarly, the Act establishes a Congressional Oversight Commission to conduct

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<sup>75</sup> *Id.*

<sup>76</sup> *Id.* § 4003(d)(1).

<sup>77</sup> *Id.* § 4003(c)(2)(D).

<sup>78</sup> *Id.* §§ 4004(a)(1), 4003(c).

<sup>79</sup> *Id.* § 4004(a)(2).

<sup>80</sup> *Id.* § 4005.

<sup>81</sup> *Id.* § 4007(a)-(c).

<sup>82</sup> *Id.* § 4019.

<sup>83</sup> *Id.* § 4018(a).

<sup>84</sup> *Id.* § 4018(c).

<sup>85</sup> *Id.* § 4018(f).

oversight of the implementation of the CESA by Treasury and the Federal Reserve.<sup>86</sup> The Oversight Commission is authorized to hold hearings, take testimony, and receive information from any federal department or agency it deems necessary.<sup>87</sup>

### *Temporary Regulatory Modifications Financial Institutions*

The CESA provides temporary modifications to certain regulations governing financial institutions. It provides the FDIC with additional authority to guarantee non-interest bearing transaction accounts and establish a debt guarantee program to guarantee debt of solvent insured depositories, from the date the CARES Act is enacted until December 31, 2020.<sup>88</sup> It similarly allows the National Credit Union Administration to increase share insurance coverage on non-interest-bearing accounts at federally insured credit unions and provides measures to enable credit unions to gain extensions of credit more easily.<sup>89</sup> It also institutes measures intended to provide temporary relief for community banks by setting the capital leverage ratio for community banks to eight percent and providing banks that fall under this ratio a grace period to satisfy the ratio requirement.<sup>90</sup>

The Act also permits financial institutions to suspend application of the Generally Accepted Accounting Principles (“GAAP”) for COVID-19-related loan modifications that would otherwise be categorized as a “troubled debt restructuring” and suspends any determination of a loan modified as a result of COVID-19 as being a “troubled debt restructuring.”<sup>91</sup> Additionally, it provides financial institutions with relief from compliance with the Federal Accounting Standards Board’s Current Expected Credit Losses accounting standard until December 31, 2020 or the termination of the declaration of the national emergency related to COVID-19.<sup>92</sup>

### **Providing Relief to Air Carrier Workers**

The CARES Act seeks to preserve aviation jobs and compensate air industry workers during the Coronavirus pandemic. The Act enables the Department of Treasury to provide financial assistance that is to be exclusively used for the payment of employee wages, salaries and benefits of passenger air carriers, cargo air carriers and contractors.<sup>93</sup> The Act allocates \$32 billion for carrying out this financial assistance.<sup>94</sup> The

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<sup>86</sup> *Id.* § 4020(a) & (b).

<sup>87</sup> *Id.* § 4020(e).

<sup>88</sup> *Id.* § 4008(a).

<sup>89</sup> *Id.* §§ 4008(b), 4016.

<sup>90</sup> *Id.* § 4012(b).

<sup>91</sup> *Id.* § 4013(a)–(c).

<sup>92</sup> *Id.* § 4014(b).

<sup>93</sup> *Id.* § 4112.

<sup>94</sup> *Id.* § 4120(a). Up to \$25 billion can be given to passenger carriers, up to \$4 billion may be given to cargo air carriers and up to \$3 billion may be given to contractors. The Secretary is permitted to use \$100 million of the allocated funds for other costs and administrative expenses associated with providing financial relief under the Act. *Id.* § 4112(a) & (b).

Act provides financial assistance equaling the amount air carriers and contractors paid out in wages, salary and benefits during the period of April 1, 2019 to September 30, 2019.<sup>95</sup> The Treasury will certify these amounts based on reporting they received by the Department of Transportation in 2019 and in some cases, financial statements or other appropriate data furnished by the air carrier or contractor seeking financial assistance.<sup>96</sup>

The Treasury has the discretion to determine the terms and conditions as well as the form in which an air carrier or contractor is to be provided with financial assistance under this provision.<sup>97</sup> Financial assistance may be conditioned on continuation of air transportation services and, in making this determination, the Department of Transportation must take into consideration the air transportation needs of small and remote communities as well as the need to maintain well-functioning health care supply chains.<sup>98</sup> In order to be eligible for financial assistance, an air carrier or contractor must enter into an agreement with the Treasury that places limitations on trading in air carrier or contractor securities, paying dividends on air carrier or contractor securities, and conducting involuntary furloughs or enact pay reductions, for a certain time period.<sup>99</sup> Additionally, air carriers and contractors that receive financial assistance under this provision must agree that they will not use aid to compensate officers and employees above a certain compensation threshold.<sup>100</sup>

The Treasury may receive financial instruments issued by recipients of financial assistance as compensation for providing such assistance.<sup>101</sup> The Treasury may not condition financial assistance on whether an air carrier or contractor enters into a collective bargaining agreement with a certified bargaining representative.<sup>102</sup>

### **Residential Mortgage Loan Protections under the CESA**

The CESA portion of the CARES Act provides a right to forbearance on residential loans and restrictions on loan servicers and lessors as follows:

- **Right to a forbearance for individuals.** The CESA provides borrowers the right to a forbearance of 180 days on federally-backed mortgage loans, with one 180-day extension period.<sup>103</sup> In order to qualify for a forbearance, the borrower must submit a request to their loan servicer and affirm

<sup>95</sup> *Id.* § 4113(a); *see also* 14 U.S.C. § 241.

<sup>96</sup> H.R. 748, § 4113. These certifications will be audited by the Inspector General of the Department of the Treasury.

<sup>97</sup> *Id.* The Secretary is authorized to set requirements for audits and claw backs of financial assistance if the air carriers or contractors fail to honor assurances.

<sup>98</sup> *Id.* § 4114(b). This authority will expire on March 1, 2022.

<sup>99</sup> *Id.* § 4114(a).

<sup>100</sup> *Id.* § 4116(a).

<sup>101</sup> *Id.* § 4117.

<sup>102</sup> *Id.* § 4115; *see also* 45 U.S.C. 151. This provision shall remain in effect until September 30, 2020.

<sup>103</sup> H.R. 748, § 4022(b)(1).

that they are experiencing a financial hardship due to COVID-19.<sup>104</sup> If the borrower qualifies, their mortgage loan servicer must grant their request.<sup>105</sup>

- **Qualifying loans:** To qualify for forbearance under the Act, a loan must be secured by a first or subordinate lien on residential real property designed principally for occupation by one to four families and must satisfy one of the following:<sup>106</sup>
  - insured by the Federal Housing Administration;
  - insured under section 255 of the National Housing Act;
  - guaranteed under section 184 or 184A of the Housing and Community Development Act of 1992;
  - guaranteed or insured by the Department of Veterans Affairs or the Department of Agriculture;
  - made by the Department of Agriculture; or
  - purchased or securitized by the Federal Home Loan Mortgage Corporation or the Federal National Mortgage Association.
- **No additional fees or interest:** The Act requires that mortgage loan servicers provide such forbearances without any additional payment, interest, penalty or requirement of information beyond the borrower's affirmation of financial hardship.<sup>107</sup> During the forbearance period and any subsequent extension periods, no interest, penalties or fees may accrue beyond those which would accrue normally, as if all payments were made fully and on time.<sup>108</sup>
- **Moratorium on foreclosures:** Under the CESA, a servicer may not initiate any judicial or non-judicial foreclosure process or execute a foreclosure-related eviction or foreclosure sale for at least the 60 day period beginning on March 18, 2020.<sup>109</sup>
- **Right to a forbearance for multifamily borrowers:** The CESA provides multifamily borrowers with federally-back loans covering properties principally designed for occupation by five or more families that were current on their payments as of February 1, 2020 the right to a forbearance of 30 days, with up to two additional 30 day extensions.<sup>110</sup> Such a borrower must affirm that they are

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<sup>104</sup> *Id.*

<sup>105</sup> *Id.* § 4022(b)(2).

<sup>106</sup> *Id.* § 4022(a).

<sup>107</sup> *Id.* § 4022(c)(1).

<sup>108</sup> *Id.*

<sup>109</sup> *Id.* § 4022(c)(2).

<sup>110</sup> *Id.* § 4023(a)–(c).

experiencing a financial hardship due to COVID-19.<sup>111</sup> The servicer must then document the affirmation and provide the forbearance as requested.<sup>112</sup>

- **Restrictions on multifamily borrowers:** A multifamily borrower may not, for the duration of such a forbearance, evict or initiate eviction of any tenant in the applicable property for reason of nonpayment or charge any late fees or penalties for late payment of rent.<sup>113</sup> They also may not require a tenant to vacate during the forbearance period or without 30 days' notice.<sup>114</sup>
- **Moratorium on evictions:** The CESA provides for a 120-day moratorium on eviction filings from the date of the enactment of the CARES Act.<sup>115</sup> This moratorium covers lessors of dwellings inhabited pursuant to a residential lease, servicers of federally-back mortgage loans and lessors of any dwellings covered by the Violence Against Women Act of 1994 or the rural housing voucher program of the Housing Act of 1949.<sup>116</sup> Such lessors are restricted from requiring tenants to vacate during the 120-day moratorium period and must provide 30 days' notice to any tenant required to vacate after that period ends.<sup>117</sup>

#### IV. Financial Assistance and Other Benefits for Individual Taxpayers

##### Cash and Tax Benefits

The CARES Act includes a number of provisions designed to provide cash and other tax benefits to individual taxpayers, including:

- **Tax rebates:** The Act provides a 2020 tax credit to eligible individual taxpayers in the amount of \$1,200 for individuals or \$2,400 for individuals filing jointly, plus an additional \$500 for each qualifying child of the taxpayer.<sup>118</sup> Each individual that would have been eligible for this credit in the 2019 tax year (or 2018 if no return was filed for 2019) is to be treated as having paid a tax in the amount of the credit, and therefore will be entitled to a refund.<sup>119</sup> The total amount to be received by a taxpayer will be phased out based on certain income thresholds, zeroing out for taxpayers making more than \$99,000 (\$198,000 in the case of a joint return).<sup>120</sup>

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<sup>111</sup> *Id.* § 4023(b).

<sup>112</sup> *Id.* § 4024(c).

<sup>113</sup> *Id.* § 4023(d).

<sup>114</sup> *Id.* § 4023(e).

<sup>115</sup> *Id.* § 4024(b).

<sup>116</sup> *Id.* § 4024(a).

<sup>117</sup> *Id.* § 4024(c).

<sup>118</sup> *Id.* § 2201(a).

<sup>119</sup> *Id.*

<sup>120</sup> *Id.*

- **Unemployment insurance benefits:** The Act provides unemployment benefits to individuals who are not traditionally eligible for unemployment benefits, who are unemployed or unable to work due to the COVID-19 emergency.<sup>121</sup> It provides otherwise eligible individuals an additional \$600 per week for up to four months and 100% funding of the first week of regular unemployment for states with no waiting period.<sup>122</sup>
- **Modifications to rules concerning retirement funds, plans, and accounts:** The Act temporarily removes the 10% additional tax normally imposed on early withdrawals from retirement funds under Internal Revenue Code § 72(t) for qualified “coronavirus-related distributions,” which are defined as any distributions, up to a maximum of \$100,000 per taxable year, from an eligible retirement plan by an individual: (i) who has been diagnosed with SARS-CoV-2 or COVID-19, whose spouse has been diagnosed with SARS-CoV-2 or COVID-19, or who is suffering adverse financial or employment consequences due to SARS-CoV-2 or COVID-19.<sup>123</sup> Loans made from such retirement accounts during the 180-day period following the enactment of the bill will not be treated as distributions so long as they do not exceed \$100,000.<sup>124</sup> The CARES Act also amends section 401(a)(9) of the Internal Revenue Code to provide for a temporary waiver of requirements related to minimum distributions under that section for certain defined contribution plans.<sup>125</sup>
- **Charitable contributions:** The CARES Act adds qualified charitable contributions of up to \$300 made by an eligible individual during the taxable year (beginning in taxable year 2020) to certain types of recipients—including medical research or educational organizations (such as hospitals)—to the list of “above the line” deductions.<sup>126</sup> The Act also temporarily suspends the percentage limitations for qualified contributions to certain types of recipients—including medical research or educational organizations (such as hospitals)—to the list of “above the line” deductions.<sup>127</sup>
- **Health services accounts:** The CARES Act amends certain sections of the Internal Revenue Code to clarify that eligibility for the health savings account deduction provided in section 223(c)(2) will not be affected by participation in a telehealth plan.<sup>128</sup>

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<sup>121</sup> *Id.* § 2101-2105.

<sup>122</sup> *Id.*

<sup>123</sup> *Id.* § 2202(a).

<sup>124</sup> *Id.*

<sup>125</sup> *Id.* § 2203.

<sup>126</sup> *Id.* § 2204(a) & (b).

<sup>127</sup> *Id.* § 2205(a).

<sup>128</sup> *Id.* § 3701(a).

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### Changes to Emergency Leave Benefits through the Families First Coronavirus Response Act and Other Labor Provisions

The CARES Act amends the emergency paid leave provisions of the FFCRA as follows:

- by clarifying that paid leave benefits under the Emergency Family and Medical Leave Expansion Act are capped at \$200 per day and \$10,000 in the aggregate *for each employee*, not total;<sup>129</sup>
- by capping the paid sick leave benefits available under the Emergency Paid Sick Leave Act at (i) no more than \$511 per day and \$5,110 in the aggregate for employees who take leave because they are subject to a quarantine order, who have been advised to self-quarantine, or who are experiencing symptoms of COVID-19 and seeking medical attention; and (ii) no more than \$200 and \$2,000 in the aggregate for employees taking leave to care for an individual subject to a quarantine order or recommendation, or a son or daughter whose school or place of care is closed, or whose caretaker is unavailable due to COVID-19.<sup>130</sup>
- by providing the Director of the Office of Management and Budget with the authority to exclude for good cause certain government employees from the provisions of the Emergency Family and Medical Leave Expansion Act and the Emergency Paid Sick Leave Act;<sup>131</sup>
- by amending the Emergency Family and Medical Leave Expansion Act to explain that “eligible employees” who may receive benefits are (i) those who have been employed for at least 30 days by the employer from whom leave is sought, including (ii) employees who were laid off after March 1, 2020, who had worked for the employer for 30 of the 60 days prior to being laid off, and were subsequently rehired;<sup>132</sup> and
- by amending the FFCRA to provide for advance payment of tax credits against amounts required to be paid by employers under the Act’s emergency leave provisions.<sup>133</sup> The due date for minimum contributions for single-employer plan funding under section 430(a) of the Internal Revenue Code of 1986 and section 303(a) or ERISA in the year 2020 is extended to January 1, 2021, with accruing interest.<sup>134</sup>

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<sup>129</sup> *Id.* § 3601.

<sup>130</sup> *Id.* § 3602.

<sup>131</sup> *Id.* § 3604(a).

<sup>132</sup> *Id.* § 3605.

<sup>133</sup> *Id.* § 3606(a).

<sup>134</sup> *Id.* § 3608(a).

Funds made available by this Act may also be used by an agency to modify contracts in order to reimburse minimum contract billing rates.<sup>135</sup> This only applies to contractors who cannot perform work approved by the Federal government, but that has been impeded by the COVID-19 emergency, and the reimbursements are not to exceed an average of 40 hours per week beyond September 30, 2020.<sup>136</sup>

### **COVID-19 Pandemic Education Relief Act of 2020**

The CARES Act includes the Pandemic Education Relief Act of 2020 (“Education Relief Act”), which provides assistance to students and institutions of higher education impacted by the COVID-19 public health emergency, and temporarily suspends student loan payments and interest on student loans for borrowers.<sup>137</sup> Most notably:

- payments for all loans held by the Department of Education and made under Part D of Title IV of the Higher Education Act of 1965 (including the federal Direct Loan and Perkins Loan programs) are suspended through September 30, 2020; and
- interest on such loans will not accrue during the suspension period, including involuntary payments.<sup>138</sup>

The Education Relief Act also relaxes restrictions on the use of federal educational aid funds to allow institutions of higher education to provide additional financial assistance to students affected by the COVID-19 emergency, including through work-study funding.<sup>139</sup>

## **V. Healthcare Response to COVID-19**

### **Addressing Supply Shortages**

The CARES Act includes a number of provisions designed to mitigate supply shortages for both drugs and medical devices, including:

- Expedited review of critical drugs and medical devices: The Act enables the Secretary of HHS to prioritize and expedite review of new devices and drugs and re-inspection of established devices and drugs if HHS determines that there is, or is likely to be, a shortage of devices or drugs that are life-supporting, life sustaining, or critical to the public health during a public health emergency.<sup>140</sup>

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<sup>135</sup> *Id.* § 3610.

<sup>136</sup> *Id.*

<sup>137</sup> *Id.* §§ 3501–3519.

<sup>138</sup> *Id.* § 3513; *see also* Higher Education Act of 1965, 20 U.S.C. § 1087 (1965).

<sup>139</sup> H.R. 748, §§ 3503, 3505, 3517–3518.

<sup>140</sup> *Id.* § 3111; 21 U.S.C. § 356c(g).

- **Reporting requirements for manufacturers of critical drugs and medical devices:** The Act requires manufacturers of certain drugs and medical devices that are critical to public health during a public health emergency to notify the U.S. Department of Health and Human Services (“HHS”) of any permanent discontinuance or interruption in manufacture of the device or an active pharmaceutical ingredient that will likely lead to meaningful disruption in the supply of the drug or device in the United States. Device manufacturers must generally report anticipated discontinuances or disruptions at least six months prior to the discontinuance or interruption, or as soon as practicable thereafter.<sup>141</sup>
- **Annual reporting requirements for drug manufacturers:** The Act requires each person registered with HHS as a manufacturer of a drug to report annually to the Secretary of HHS the amount of each drug it manufactured, prepared, propagated, compounded or processed for commercial distribution. HHS has the authority to exempt certain biological products from these reporting requirements if he determines that reporting would not be necessary to protect the public health.<sup>142</sup>
- **Risk management plans:** The Act requires manufacturers of critical drugs, pharmaceutical ingredients, and any associated medical devices to develop and enact risk management plans that identify and evaluate risks to the supply of a drug or active pharmaceutical ingredient.<sup>143</sup>
- **Immunity from suit for “covered persons” under the Public Health Service Act:** The Strategic National Stockpile provisions in the Public Health Service Act provide immunity from suit and liability to “covered persons,” including the United States and certain manufacturers and distributors, for claims arising out of the administration of “covered countermeasure[s].” Prior to the passage of the CARES Act, “covered countermeasures” included certain pandemic or epidemic products, security measures, drugs, and biological products for emergency use. The Act amends the definition of “covered countermeasures” to also include certain respiratory protective devices.<sup>144</sup>

### **Increasing Access to Health Care**

With respect to private healthcare plans, the Act amends the Families First Coronavirus Response Act’s (“FFCRA”) no-cost COVID-19 testing requirements and requires no-cost immunization.<sup>145</sup> Additionally, the Act provides for certain liability protections for healthcare providers who volunteer during the public

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<sup>141</sup> H.R. 748, §§ 3112 (reporting requirements for manufacturers of drugs), 3121 (reporting requirements for manufacturers of devices).

<sup>142</sup> *Id.* § 3112.

<sup>143</sup> *Id.*

<sup>144</sup> *Id.* § 3103; 42 U.S.C. 247d–6d(i)(1).

<sup>145</sup> See Paul, Weiss Client Memorandum, Congress Passes COVID-19 Relief Package (Mar. 18, 2020), available [here](#).

health emergency and adds certain patient record confidentiality requirements. Lastly, the Act appropriates \$2.54 billion for community health centers and certain telehealth and rural healthcare programs.

- **Expanded private plan coverage for no-cost COVID-19 testing:** The Act expands the FFCRA’s no-cost testing requirements for group health plans or health insurance issuers offering group or individual health insurance (“private healthcare plans”) to include not only FDA-approved tests for COVID-19, but also: (i) tests for which the developer has requested or intends to request emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act; (ii) state-developed labs; and (iii) any other test that the HHS determines is appropriate in guidance.<sup>146</sup> Consistent with the FFCRA’s no-cost testing requirements, coverage of these added categories of COVID-19 testing is not subject to any deductible, co-pay, or requirement for pre-authorization and is applicable for the duration of the COVID-19 public health emergency period from the date the Act is enacted.<sup>147</sup> The CARES Act requires private healthcare plans to reimburse the provider of COVID-19 diagnostic testing at the negotiated rate in effect prior to the COVID-19 public health emergency.<sup>148</sup> If no negotiated rate is in place with the applicable provider, the reimbursement must be the cash price of the service published on the provider’s public website, on which providers must publicize the price during the COVID-19 public health emergency.<sup>149</sup>
- **Private plan coverage for no-cost COVID-19 preventative care:** Group health plans and health insurance issuers offering group or individual health insurance must cover on a permanent basis, at no cost to covered individuals, any “qualifying coronavirus preventative service,” defined as any item, service or immunization to prevent or mitigate a coronavirus disease that is (i) an item or service that is evidence-based and rated A or B under a U.S. Preventative Services Task Force recommendation or (ii) any immunization recommended by the U.S. Centers for Disease Control and Prevention for the individual involved.<sup>150</sup> Coverage for immunizations will begin 15 business days after the applicable recommendation of an item, service, or immunization is issued.<sup>151</sup>
- **Liability limitations for volunteer healthcare providers:** The Act limits federal and state law liability for licensed, registered, or certified health care professionals who volunteer during the public health emergency.<sup>152</sup> The liability limitation applies to acts or omissions in providing services relating to the diagnosis, prevention, or treatment of COVID-19 or the assessment or care of the health of a human being related to an actual or suspected case of COVID-19, where such services are within the scope of the volunteer’s license, registration, or certification and are provided with a

<sup>146</sup> H.R. 748, § 3201.

<sup>147</sup> See FFCRA, H.R. 6201, § 6001(a).

<sup>148</sup> H.R. 748, § 3202.

<sup>149</sup> *Id.*

<sup>150</sup> *Id.* § 3203(a) & (b)(1).

<sup>151</sup> *Id.* § 3203(b)(2); 42 U.S.C. § 300gg-13.

<sup>152</sup> H.R. 748, § 3215(a).

good faith belief that the treated individual requires health care services.<sup>153</sup> The liability limitations are subject to exceptions for harm resulting from willful or criminal misconduct or gross negligence, and are applicable to covered healthcare services rendered from the enactment of the Act until the end of the COVID-19 public health emergency.<sup>154</sup>

- **Confidentiality for patient records:** The CARES Act also requires HHS to issue guidance on sharing protected patient information and compliance with HIPAA during the public health emergency period.<sup>155</sup> Separately, the Act addresses confidentiality requirements in connection with medical information for patients with a substance abuse disorder.<sup>156</sup>
- **Support for health care and other programs:** The Act provides for \$1.32 billion for fiscal year 2020 for federal loan guarantees to community health centers serving medically underserved populations for detecting, preventing, diagnosing and treating COVID-19. The Act also provides, in each of fiscal years 2021 through 2025: \$29 million for telehealth projects for rural and medically underserved areas; \$79.5 million for rural health and small health care provider quality improvement grant programs; and \$125.5 million for the Healthy Start program.

### Regulation of Nonprescription Drugs

The CARES Act amends the Federal Food, Drug, and Cosmetic Act<sup>157</sup> (“FDCA”) to include new regulations for certain nonprescription drugs marketed without an approved drug application.<sup>158</sup> The Act provides the procedures by which HHS may issue administrative orders about requirements for various drugs on the market as well as the procedures for formal adjudication of decisions regarding various drug requirements. These procedures include the following:

- The new regulations permit certain drugs or combinations of drugs not to require approval under section 505 of the FDCA. These drugs include, among other things, drugs that the HHS determines are in conformity with the requirements for nonprescription use of a final monograph, are marketed in conformity with an administrative order determining that it is generally recognized as safe and does not require approval, or meet the general requirements for nonprescription drugs.<sup>159</sup>

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<sup>153</sup> *Id.* § 3215(a) & (c).

<sup>154</sup> *Id.* § 3215(b), (e) & (f).

<sup>155</sup> *Id.* § 3224.

<sup>156</sup> *Id.* § 3221.

<sup>157</sup> 21 U.S.C. § 355g.

<sup>158</sup> H.R. 748, § 3851(a).

<sup>159</sup> *Id.*

- The CARES Act also provides expedited procedures for administrative orders issued by HHS regarding drugs that pose an imminent hazard to public health.<sup>160</sup> Expedited procedures for such administrative orders are also available when a change in the labeling of a drug—such as new warnings or other information required for the safe use of the drug—is reasonably expected to mitigate a serious or unreasonable risk of adverse events associated with the use of the drug.<sup>161</sup> In such cases, HHS may issue an interim final administrative order and need only make reasonable efforts to notify sponsors who have a listing for the drug at issue not later than 48 hours before the issuance of the order.<sup>162</sup>
- The CARES Act amends the procedures for filing a request that a non-prescription drug is generally recognized as safe and effective.<sup>163</sup> In response to a such a request for nonprescription drugs that contain an active ingredient not previously incorporated in certain drugs, HHS may: (i) file such request if the request includes specified information demonstrating prima facie safe nonprescription marketing and use of such drug; or (ii) may refuse to file such request and require that nonprescription marketing of the drug be pursuant to a new drug application.<sup>164</sup>
- The CARES Act also provides that an administrative order issued by HHS may include packaging requirements to encourage use in accordance with labeling, including unit dose packaging, requirements for products intended for pediatric use and other appropriate requirements.<sup>165</sup>
- Minor changes in the dosage form of a drug may be made by a requestor without the issuance of an order if the requestor shows that the change: (i) will not affect the safety or effectiveness of the drug; (ii) will not materially affect the extent of absorption or other exposure to the active ingredient in comparison to a suitable reference product; and (iii) the change is in conformity with the requirements of an applicable administrative order issued by HHS.<sup>166</sup> A sponsor who makes a change to a drug subject to this provision must submit updated drug listing information with the drug in accordance with section 510(j) before the drug is first commercially marketed.<sup>167</sup>

### **Drug Innovations to Combat Infectious Disease**

The Public Health Service Act mandates that HHS develop a strategic plan to integrate biodefense and emerging infectious disease requirements with advanced research and development, strategic initiatives,

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<sup>160</sup> *Id.*  
<sup>161</sup> *Id.*  
<sup>162</sup> *Id.*  
<sup>163</sup> *Id.*  
<sup>164</sup> *Id.*  
<sup>165</sup> *Id.*  
<sup>166</sup> *Id.*  
<sup>167</sup> *Id.*

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and the procurement of qualified countermeasures and pandemic products.<sup>168</sup> The CARES Act provides that, to the maximum extent possible, HHS shall use competitive procedures when entering into transactions to carry out projects under the strategic plan that are related to a public health emergency.<sup>169</sup>

Under the CARES Act, HHS may also expedite the review and development of a new drug if the evidence suggests that the drug, either alone or in combination with other drugs, has the potential to prevent or treat a disease that is transmitted from animals to humans and has the potential to cause serious adverse health consequences for, or serious or life-threatening diseases in, humans.<sup>170</sup>

### **Amendments to the Social Security Act**

The CARES Act amends the Social Security Act by, among other things, easing the face-to-face meeting requirements between Medicare/Medicaid recipients and their medical care providers, which were previously necessary for the medical care providers to receive payment.<sup>171</sup>

We will continue to monitor developments and keep clients apprised of pertinent information.

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<sup>168</sup> 42 U.S.C. § 247d–7e.

<sup>169</sup> H.R. 748, § 3301.

<sup>170</sup> *Id.* § 3302.

<sup>171</sup> *See, e.g., id.* § 3705.

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This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. Questions concerning issues addressed in this memorandum should be directed to:

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