



## **COVID-19 Regulatory Policy Resource Guide**

*As of June 5, 2020*

*7wireVentures provides U.S. digital health startups with the information they need to know about the new COVID-19 legislation and how these regulations impact their business*

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## I. Summary of Relevant Legislation Changes for Digital Health Startups

In response to COVID-19, several regulatory and reimbursement policies have been passed that directly impact digital health startups. Companies should understand the immediate implications to their respective businesses, both positive and negative, as well as the resources they can leverage. While we encourage you to read this guide in its entirety, the below summarizes the core changes for startups to take away for their respective organizations.

There are **several financial resources** available to small businesses as a result of federal and state level legislation. Startups should evaluate eligibility for these financial stimulus programs and apply immediately.

- **[Small Business Administration – Economic Injury Disaster Loans \(EIDLs\)](#)**: EIDL’s are working capital loans of up to \$2 million for small businesses to help overcome a temporary loss of revenue. Loans have interest rates of 3.75% and are subject to personal guarantees (above \$200K), evaluations of credit worthiness, and affiliation rules.
  - a. **Important Considerations**: Affiliations include investors with majority ownership or deemed to have “control” over a board or operations. These investors and their controlled portfolio companies must be included in the total employee count used to determine eligibility.
- **[Paycheck Protection Program \(PPP\) Loans](#)**: A \$349 billion stimulus package has been made available to support SMBs, self-employed individuals, and non-profits. An additional \$310 billion was approved on April 24, 2020. The program permits unsecured loans up to 2.5x average monthly payroll expenses (total amount capped at \$10 million). Loans are forgivable up to 100% of the principal amount if a company retains its full-time employees and does not reduce salaries or wages. Loan proceeds can be used for rent, utilities, and interest on mortgage and other debt obligations.
  - **Important Considerations**: SBA affiliation rules apply and may impact eligibility. The monthly payroll calculation excludes *cash* compensation paid to individual employees in excess of \$100,000 and includes payments to independent contractors. Receiving SBA loans through the [PPP program](#) will impact eligibility for some tax benefits offered through other parts of the CARES Act.
  - **\*Updates\*** New guidance on [April 23, 2020](#) stipulates that companies must take into account “current business activity and their ability to access other sources of liquidity” when certifying in good faith that the loan is necessary. Additionally, on April 28, 2020 the U.S. Department of Treasury noted that all loans taken above \$2 million will be subject to a full audit before the loan is forgiven.
  - **\*Updates\*** On [April 30, 2020](#), the IRS released a notice stating that expenses that would otherwise be deductible for federal income tax purposes shall be disallowed to the extent of any related PPP loan forgiveness.
  - **\*Updates\*** On [May 1, 2020](#), the Small Business Administration (SBA) released guidance that businesses that are part of a single corporate group shall in no event receive more than \$20 million of Paycheck Protection Program (PPP) loans in the aggregate.
  - **\*Updates\*** On [May 7, 2020](#), the U.S. Department of Treasury released guidance extending the safe harbor period to repay PPP loans until May 14, 2020. Additionally,

the Treasury clarified that an applicant must count all of its employees and the employees of its U.S. and foreign affiliates, absent a waiver of or an exception to the affiliation rules.

- **\*Updates\*** On May 13, 2020, the [U.S. Department of Treasury released guidance](#) that any borrower that, together with its affiliates, received PPP loans with an original principal amount of less than \$2 million will be deemed to have made the required certification concerning the necessity of the loan request in good faith.
- **\*Updates\*** On June 5, 2020, the [Paycheck Program Flexibility Act](#) (PPFA) was signed into law, relaxing certain deadlines and standards, and providing borrowers additional flexibility in the use of PPP funds.

As part of this federal legislation passed, there are **multiple tax relief provisions** oriented toward improving the after-tax cash flow of businesses and encouraging companies to retain their current workforces.

- **[Social Security Payroll Tax Deferment](#)**: Businesses can defer Social Security payroll taxes for the remainder of 2020, and instead pay 50% in 2021 and 50% in 2022. Companies who receive loans under the [PPP](#) program are ineligible.
- **[Employee Retention Tax Credit](#)**: A refundable tax credit is made available to employers from March 12, 2020 through January 1, 2021 to cover the 6.2% Social Security payroll tax expense. The tax credit covers up to 50% of the first \$10,000 in qualified wages (including health plan expenses) paid to each employee (i.e., \$5,000 per employee). Companies who receive loans under the [PPP](#) program are ineligible.
- **[FFCRA Tax Credit for Sick Leave and Family and Medical Leave](#)**: A quarterly payroll tax credit is being made available to cover 100% of any additional sick and family leave paid out and the new policies enacted by the Family First Coronavirus Relief Act (FFCRA).

In an attempt to support employees, federal legislation has **mandated additional sick and family medical leave and has expanded unemployment benefits** for workers.

- **[Paid Sick Leave \(EPSLA\)](#)**: Employers with fewer than 500 employees must offer 2 weeks of paid sick leave to employees impacted by COVID-19 through December 31, 2020.
- **[Paid Family Medical Leave \(EFMLA\)](#)**: Employers with fewer than 500 employees must provide up to 12 weeks of paid leave for employees who are unable to work or telework because they must care for a minor. Exceptions are also available for companies with fewer than 50 employees and companies that provide healthcare and emergency services.
- **[Unemployment Insurance Benefits](#)**: Maximum unemployment benefits have been extended by one month (now 4 months); an additional \$600 per week has been added for all unemployment filers.

CMS has authorized a list of **regulatory requirement waivers** to expand the capacity of the health care system and allow providers to focus on delivering care safely.

- **[Telemedicine Expansion](#)**: Access to telehealth services can be provided for Medicare consumers via telephones, smart phone applications, or laptops. Patients can be reached directly in their homes regardless of geographic location and without demonstrating prior patient-physician relationships.

- **Expansion of the Health Care Workforce**: Companies can virtually service geographies with providers licensed in a separate state for Medicare and in some cases Medicaid. Self-quarantined or part-time clinicians can be employed to deliver care virtually. Health systems can provide care based on population management strategies, such as triaging by COVID-19 and clinical status, to better manage patient volumes.

In response CMS's policy changes, **commercial payers have followed suit** by taking action to expand reimbursement and increase access. The most common responses include:

- **COVID-19 Coverage**: Waiving cost-sharing or prior authorizations for COVID-19 screening or diagnostic testing, and for in-patient treatment of COVID-19 or complications.
- **Telehealth Coverage**: Encouraging use of telehealth services through enhanced marketing of services and provision of resource pages. Some payers are expanding access to telehealth by increasing services and groups covered, enhancing internal systems, or increasing partnerships with vendors. Finally, many organizations have waived cost-sharing of telehealth services.
- **Mental Health Coverage**: Providing behavioral health appointments or programs to manage stress and anxiety.
- **Prescription Coverage**: Relaxing prescription refill limits or encouraging the use of home delivery services.

## II. Congressional Acts

### a. Coronavirus Preparedness and Response Supplemental Appropriations Act

<b>Passed Date</b>	3/6/2020
<b>Policy</b>	Legislation passed to provide an \$8.3 billion package including an emergency telehealth waiver, vaccine development, support for state and local governments, and assistance for affected small businesses.
<b>Goal</b>	To provide funding for the country's response to COVID-19.
<b>Overview</b>	<p><b>Domestic Funding</b></p> <ul style="list-style-type: none"> <li>• <b>Funding for the Food and Drug Administration (FDA) - \$61M</b> <ul style="list-style-type: none"> <li>○ Development of necessary medical countermeasures and vaccines, advanced manufacturing for medical products, the monitoring of medical product supply chains, and related administrative activities</li> </ul> </li> <li>• <b>Funding for the Small Business Administration - \$20M</b> <ul style="list-style-type: none"> <li>○ Administration of <a href="#">Economic Injury Disaster Loans (EIDLs)</a> available under "Disaster Loans Program Account"</li> <li>○ \$1B in loan subsidies available to help small businesses, which could enable \$7B in loans</li> </ul> </li> <li>• <b>Funding for the Centers for Disease Control and Prevention (CDC) - \$1.9B</b> <ul style="list-style-type: none"> <li>○ Grants to carry out surveillance, epidemiology, lab capacity, infection control, mitigation, communications, and other preparedness and response activities</li> <li>○ \$300M for global disease detection and emergency response</li> <li>○ \$300M for the Infectious Diseases Rapid Response Reserve Fund</li> <li>○ Grants for construction, alteration, or renovation of non-Federally owned facilities to improve preparedness and response capability at state and local levels</li> </ul> </li> <li>• <b>Funding for the National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases - \$836M</b> <ul style="list-style-type: none"> <li>○ Funds for worker-based training to prevent and reduce exposure of hospital employees, emergency first responders, and other workers who are at risk of exposure to COVID-19 through their work duties</li> </ul> </li> <li>• <b>Funding for the Public Health and Social Services Emergency Fund - \$3.4B</b> <ul style="list-style-type: none"> <li>○ \$3.1B for the development of necessary countermeasures and vaccines, prioritizing platform-based technologies with U.S.-based manufacturing capabilities, and the purchase of vaccines, therapeutics, diagnostics, necessary medical supplies, medical surge capacity, and related administrative activities</li> <li>○ An additional \$300M will be available for the purchase of vaccines, therapeutics, and diagnostics if needed</li> </ul> </li> <li>• <b>Emergency Telehealth Waiver - \$500M</b> <ul style="list-style-type: none"> <li>○ Medicare providers may provide telehealth services to Medicare beneficiaries who are located at home rather than a</li> </ul> </li> </ul>

	<p>designated facility and regardless of whether the beneficiary is in a rural community (waives both originating site and geographic requirements)</p> <ul style="list-style-type: none"> <li>○ Telehealth services can be provided via telephone as long as it has audio and video capabilities for two-way, real-time interactive communication (waives telephone restriction)</li> </ul> <p><b>International Funding</b></p> <ul style="list-style-type: none"> <li>● <b>Funding for the United States Agency for International Development (USAID) - \$986M</b> <ul style="list-style-type: none"> <li>○ \$435M for Global Health Programs (GHP) to support health systems responding to the coronavirus outbreak overseas</li> <li>○ \$300M for International Disaster Assistance (IDA) to support humanitarian assistance needs from the outbreak</li> <li>○ \$250M for the Economic Support Fund (ESF) to support economic, security, and stabilization efforts</li> <li>○ \$1M for the Office of the Inspector General (OIG) for oversight of coronavirus response activities</li> </ul> </li> <li>● <b>Funding for the State Department to support consular operations, emergency evacuations, and other needs at U.S. embassies - \$264M</b> <ul style="list-style-type: none"> <li>○ Support of consular operations, emergency evacuations, and other needs at U.S. embassies</li> </ul> </li> <li>● <b>Funding for the Centers for Disease Control and Prevention (CDC) - \$300M</b> <ul style="list-style-type: none"> <li>○ Support of global disease detection and emergency response efforts</li> </ul> </li> </ul>
<b>Business Benefits</b>	<ul style="list-style-type: none"> <li>● Strengthening of U.S. medical product manufacturing sector by supporting efforts to foster more investment and innovation in advanced manufacturing methods for drugs, devices, vaccines, and other therapies</li> <li>● Enables businesses to apply for emergency funding through the <a href="#">EIDLs program</a> (details below)</li> </ul>
<b>Individual Level Benefits</b>	<ul style="list-style-type: none"> <li>● More accurate maintenance of national drug and device product inventory</li> <li>● Additional support for surveillance, testing, contact tracing, infection control, and other preparedness and response activities</li> <li>● Availability of vaccines, therapeutics, and diagnostics on the commercial market at affordable prices</li> <li>● Receipt of care from physicians and other practitioners in patients' homes</li> </ul>
<b>Digital Health Startup Implications</b>	<ul style="list-style-type: none"> <li>● <b>SBA Economic Injury Disaster Loans (EIDLs)</b> are working capital loans of up to \$2M to help overcome temporary loss of revenue</li> <li>● Loans will have a 3.75% interest rate and are subject to personal guarantees (above \$200K), credit worthiness (ability to repay), and affiliation rules (see below). Companies with equity investors are required to aggregate all the companies they are affiliated with when defining the number of employees for the loan applicant</li> </ul>

	<ul style="list-style-type: none"> <li>• <b>Special Note: Affiliation Rules</b> - Standard SBA Affiliation rules apply to venture-backed companies looking to obtain an EIDL (affiliation rule details can be found <a href="#">here</a> and <a href="#">here</a>) <ul style="list-style-type: none"> <li>○ A company may be considered an “affiliate” of an investor if that investor either (a) maintains majority ownership (multiple definitions), or (b) is deemed to have “control” over the governing board or the operations of the company</li> <li>○ If a company is deemed to be an “affiliate” of one or more of its investors, then the employees of the affiliated investor(s) and potentially the employees of the investor’s other portfolio companies will be included in the total employee count that is used to determine eligibility for the EIDL</li> </ul> </li> <li>• U.S. small and medium businesses (companies with fewer than 500 employees) that meet affiliation guidelines are eligible</li> <li>• EIDLs can be rolled into <a href="#">PPP loans</a> but are less of a fit for venture-backed startups given the more stringent underwriting requirements and non-forgivable nature</li> </ul>
<b>Action Items</b>	<ul style="list-style-type: none"> <li>• Consider your affiliation eligibility; identify all affiliates and provide certain eligibility certifications in the loan application. Determinations should be made carefully and thoughtfully</li> <li>• Work with your bank to apply for an SBA loan right away; commercial banks began taking applications beginning 4/1/2020</li> <li>• If you have already applied, wait before signing the loan agreement - discuss with your accountant and lawyer the trade-offs between pursuing a <a href="#">PPP loan</a> and an <a href="#">EIDL</a></li> </ul>
<b>Sources</b>	<ul style="list-style-type: none"> <li>• <a href="#">Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020</a></li> <li>• <a href="#">H.R. 6074 Title-By-Title Summary</a></li> <li>• <a href="#">NVCA Affiliation in the Context of SBA Loans – Guidance for Venture Capital Investors</a></li> </ul>



## b. Families First Coronavirus Response Act

<b>Passed Date:</b>	3/18/2020 [effective 4/1/2020]
<b>Expiration Date:</b>	12/31/2020 (or expiration of national emergency declaration)
<b>Policy</b>	Provides emergency benefits for individuals and families impacted by the coronavirus emergency and sets mandates for small and medium sized businesses; the Act covers topics including paid sick and family leave, unemployment benefits, tax credits, testing coverage, and nutrition assistance.
<b>Goal</b>	To address employer paid leave for individuals who have been or will be adversely affected by COVID-19 and to provide economic resources for companies to support impacted employees.
<b>Overview</b>	<ul style="list-style-type: none"> <li>• <b>Emergency Unemployment Insurance Stabilization and Access Act of 2020 (\$1B)</b> <ul style="list-style-type: none"> <li>○ Provides interest-free loans to states to assist with payment of unemployment compensation benefits through December 31, 2020</li> <li>○ Act eliminates the need for employees to wait a week before they are eligible for unemployment benefits and eases work search requirements (i.e., employees will be able to apply more quickly)</li> </ul> </li> <li>• <b>Emergency Family and Medical Leave Expansion Act (EFMLEA):</b> <ul style="list-style-type: none"> <li>○ Employers with fewer than 500 employees will need to provide up to 12 weeks (10 weeks paid, 2 weeks unpaid) of FMLA leave for employees who have been on the job for at least 30 days, and who are unable to work or telework because they have to care for a child due to the COVID-19</li> <li>○ The first 10 days of leave can be unpaid (a worker could opt to use accrued vacation days or other available paid leave for those days); for the remaining 10 weeks, employees will receive a benefit equal to at least two-thirds of their normal pay rate</li> <li>○ Paid leave is capped at \$200 per day and \$10,000 in aggregate</li> <li>○ Employers with 25+ employees should ensure that the person who goes on leave is restored to their same position once the leave ends</li> <li>○ Wages paid under the emergency FMLA provisions will not be subject to the 6.2% social security payroll tax</li> <li>○ <b>Exceptions:</b> Businesses with <u>fewer than 50 employees</u> may be exempt from these requirements if they can prove that providing the leave would jeopardize viability of the business</li> <li>○ <b>Exceptions:</b> Healthcare providers and emergency response organizations may exclude employees from paid FMLA expansion</li> <li>○ <b>Exceptions:</b> The requirement to restore an employee to their prior position does not apply to employers with fewer than 25 employees if the position held by the employee on leave no longer exists due to conditions caused by the coronavirus pandemic, and the employer makes reasonable efforts to restore the employee to an equivalent position</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>• <b>Emergency Paid Sick Leave Act (EPSLA)</b> <ul style="list-style-type: none"> <li>○ Employers with fewer than 500 employees must offer 2 weeks of paid sick leave to employees impacted by COVID-19 through December 31, 2020</li> <li>○ Full-time employees are to receive 80 hours of sick leave, and part-time workers are granted leave equivalent to their average hours worked in a two-week period, with the sick leave in either instance being available regardless of the employee’s tenure at the employer</li> <li>○ Employees are eligible if they display symptoms, are subject to quarantine orders, are advised to self-quarantine, or are responsible for caring for someone who meets these criteria</li> <li>○ Sick leave is to be paid out at the employee’s regular rate if an employee has symptoms or is subject to quarantine; capped at \$511 per day and \$5,110 total (over a 2-week period)</li> <li>○ Sick leave is to be paid at two thirds the employee’s regular rate if they are the caregiver for someone who displays symptoms, is subject to quarantine orders, or is advised to self-quarantine; capped at \$200 per day and \$2,000 total (over a 2-week period)</li> <li>○ Wages paid under the emergency sick leave provisions will not be subject to the 6.2% social security payroll tax</li> <li>○ Employers will have to post a notice containing the emergency sick leave provisions</li> </ul> </li> <li>• <b>Tax Credit to Cover Expanded Paid FMLA and Sick Leave</b> <ul style="list-style-type: none"> <li>○ Sick and family leave paid out due to COVID-19 will be 100% reimbursed via a payroll tax credit on the company’s next quarterly payroll filing</li> <li>○ The sick leave credit for each employee will be for wages (including qualified health plan expenses relating to those wages) of up to \$511 per day while the employee is receiving paid sick leave to care for himself or herself, or \$200 if caring for a family member or child whose school has closed; capped at 10 days per employee per quarter</li> <li>○ The family leave credit for each employee will be for wages (including qualified health plan expenses relating to those wages) of as much as \$200 per employee per day</li> <li>○ Employers must include the amount of credits received in their reported gross income</li> <li>○ An employer can elect to not take the credit for a given quarter</li> <li>○ If tax offset is not enough to cover payouts to employees, the Treasury Department is authorized to help cover the rest with cash payments</li> </ul> </li> </ul>
<b>Business Benefits</b>	<ul style="list-style-type: none"> <li>• Provides tax credits to offset mandatory paid sick and family leave requirements</li> </ul>
<b>Individual Level Benefits</b>	<ul style="list-style-type: none"> <li>• Provides enhanced unemployment and paid leave benefits for the remainder of the calendar year</li> </ul>

<p><b>Digital Health Startup Implications</b></p>	<ul style="list-style-type: none"> <li>• The emergency expansion of paid sick and family leave applies to a majority of private companies with 500 or fewer employees. However, some exceptions are made for companies with fewer than 50 employees and companies that provide healthcare and emergency services; check with posted guidelines from the Department of Labor for exemption details (expected to be available in April 2020)</li> <li>• Companies should be compliant with all requirements and should evaluate their specific situations to understand applicability of available tax credits and potential trade-offs between FMLA and potential furloughs or layoffs, for both employees and the company</li> </ul>
<p><b>Sources:</b></p>	<ul style="list-style-type: none"> <li>• <a href="#">U.S. Department of Labor Families First Coronavirus Response Act: Employer Paid Leave Requirements</a></li> <li>• <a href="#">National Law Review: Senate Passes Families First Coronavirus Response Act: What Employers Need to Know</a></li> <li>• <a href="#">KFF The Families First Coronavirus Response Act: Summary of Key Provisions</a></li> </ul>

### c. Coronavirus Aid, Relief, and Economic Security (CARES) Act

Passed Date	3/27/2020 4/24/2020 ( <i>additional PPP funding approved</i> )
Expiration Date:	12/31/2020 (or expiration of national emergency declaration)
Policy	The act builds on the two previously passed pieces of legislation to provide economic simulation and more robust support to individuals and businesses through tax policies, loan programs, expanded unemployment insurance regulations. The act also expands access to healthcare through a series of emergency Medicare, Medicaid and telehealth policy changes and waivers.
Goal	Broad measures to support the economy as it suffers from the negative impacts of the COVID-19 pandemic.
Overview	<ul style="list-style-type: none"> <li>• <b>Note:</b> <i>While the full CARES Act contains additional programs and provisions, this document focuses on select components of the act with that have outsized impact on SMBs and digital health companies</i></li> <li>• <b>Paycheck Protection Program (PPP) - \$349B</b> <b>4/24 Update: Additional \$310B approved</b> <ul style="list-style-type: none"> <li>○ \$349 billion is being made available to SMBs and non-profits through the Paycheck Protection Program (PPP)</li> <li>○ <b>4/24 Update:</b> An additional \$310 billion of funding for the PPP was approved on April 24, 2020</li> <li>○ <b>4/24 Update:</b> \$60 billion of the new funding (approved on 4/24) has been designated to support lending from small banks and credit unions (i.e., \$30 billion for lenders with &lt;\$10 billion in assets, \$30 billion for lenders with assets between \$10 billion and \$50 billion)</li> <li>○ The program covers all SBA 7(a) loans made between February 15, 2020 and June 30, 2020 (i.e., the end of the program term)</li> <li>○ Loans will be administered by the United States Small Business Administration (SBA) and a network of approved lenders</li> <li>○ Lenders began processing PPP loan applications on April 1, 2020 (processing and approval timelines will vary by lender)</li> <li>○ In general, companies will qualify for the loans if they meet the following requirements:           <ul style="list-style-type: none"> <li>▪ In operation on February 15, 2020</li> <li>▪ Have no more than 500 employees</li> <li>▪ Can demonstrate in good faith that the loan request is necessary due to the pandemic (<b>see update below</b>)</li> </ul> </li> <li>○ <b>4/24 Update: IMPORTANT</b> The additional \$310 billion in funding for the PPP comes with new guidance for lenders that stipulates borrowers must take into account their ability to access other sources of liquidity that may be sufficient to support their ongoing operations when demonstrating necessity of the loan (i.e., companies must consider their ability to access other funding)           <ul style="list-style-type: none"> <li>▪ <b>Note:</b> This new requirement may impact venture-backed companies' ability to access funding under the PPP if it is deemed that they are able to access sufficient funding from public or private capital markets, therefore negating the</li> </ul> </li> </ul> </li> </ul>

“necessity” of the loan; companies should consult with legal counsel and their lenders to determine how these new requirements impact their eligibility

- **NOTE:** The U.S. Treasury provided guidance and extended the safe harbor date, noting that “Any borrower that applied for a PPP loan prior to the issuance of this guidance and repays the loan in full by May 14, 2020 will be deemed by SBA to have made the required certification in good faith.”
- Additionally, the U.S. Treasury released guidance that any borrower that, together with its affiliates, received PPP loans with an original principal amount of less than \$2 million will be deemed to have made the required certification concerning the necessity of the loan request in good faith.
- Companies can access unsecured loans for **2.5 times the average total monthly payroll for the last year** with the total amount capped at \$10 million
  - **Note:** Monthly payroll calculation includes payments to independent contractors and excludes cash compensation paid to individual employees above \$100,000 (Note: the \$100,000 cap only applies to cash compensation and does not apply to non-cash benefits, such as health plan benefits, employer contributions to retirement plans, etc.)
  - **4/29 Update:** The U.S. Department of the Treasury announced that PPP loans taken above \$2 million will be audited before there is loan forgiveness. The audit will certify that the loan was taken in good faith and necessary for the business to maintain ongoing operations.
  - **5/1 Update:** The Small Business Administration (SBA) released additional guidance that businesses that are part of a single corporate group shall in no event receive more than \$20 million of Paycheck Protection Program (PPP) loans in the aggregate.
  - **5/2 Update:** The U.S. Department of the Treasury provided guidance on the employee count when determining loan eligibility. The new guidance clarifies that for the purpose of the PPP’s 500 or fewer employee size standard, an applicant must count all of its employees and the employees of its U.S. and foreign affiliates.
  - **6/5 Update:** The PPPFA provided additional flexibility on use of proceeds for payroll. The act reduced the total amount of loan proceeds that must be used for covered payroll expenses from 75% to 60% and, conversely, increases to 40% (from 25%) the amount of the loan proceeds that may be used for covered non-payroll expenses.
- Interest rates will be capped at 4% and no payments are required for the first 6 months

- Unlike disaster loans, these loans are forgivable up to 100% of the principal amount borrowed if the company retains all of its full-time employees (FTEs) and does not reduce salaries or wages
- Loan proceeds can be used for payroll, rent, utilities, and interest on mortgage and other debt obligations
  - **Note:** Payroll includes costs for vacation, parental, family, medical, and sick leave, however, sick and family leave benefits provided under the FFCRA are excluded
- **4/30 Update:** The IRS released a notice stating that expenses that would otherwise be deductible for federal income tax purposes shall be disallowed to the extent of any related PPP loan forgiveness.
- **6/5 Update:** The [PPPFA](#) resulted in meaningful changes regarding loan maturity and loan forgiveness.
  - Loan maturity for unforgiven portion of a PPP loan made after the effective date of the PPPFA legislation will be extended from 2 years to 5 years. Borrowers and lenders can agree to modify the terms of loans issued previously.
  - The "covered period" for calculating forgiveness amounts has been extended from the eight weeks from loan origination until the earlier December 31, 2020, or 24 weeks from loan origination.
  - Extends the timeframe for which borrowers can rehire employees from June 30, 2020 to December 31, 2020 and thereby limit reductions in forgiveness.
  - A reduction in a borrower's forgiveness amount associated with reductions in headcount during the covered period is not applicable to the extent the borrower can document in good faith that (1) The borrower is unable to rehire employees who worked for the borrower as of February 15, 2020 or hire similarly qualified employees for unfilled positions on or before December 31, 2020, or (2) The borrower is unable to return to the same level of activity as existed on February 15, 2020 due to requirements issued by the HHS, the CDC, or OSHA from March 1, 2020 through December 31, 2020.
- **6/5 Update:** The [PPPFA](#) also resulted in changes to loan repayment extending the deferral of payments on principal and interest (originally set at 6 months) until the date on which SBA remits the forgiveness amount back to the lender, or if forgiveness isn't sought within 10 months after the last day of the "covered period."
- PPP loans may also be used to refinance an existing SBA 7(a) loan taken out on or after January 31, 2020 and received before loans under the PPP became available
- Unlike other SBA loans, the borrower does *not* need to show that it is unable to obtain credit elsewhere
- The SBA will encourage lenders to prioritize borrowers in underserved and rural markets (e.g., businesses owned by socially

and economically disadvantaged individuals, veterans, and women, and businesses less than two years old)

- The SBA will allow approved lenders to make eligibility determinations themselves based on the supplied criteria; most lending institutions are prioritizing current clients when processing loan applications
- **SBA Disaster Loans (EIDL)**: A borrower that has taken out an SBA Economic Injury Disaster Loan (EIDL) for purposes other than payroll costs and the select other uses ) between January 31, 2020, and the date Paycheck Protection Loans are first made available will continue to be eligible for an additional loan through the PPP
- **SBA Disaster Loans (EIDL)**: A borrower that has taken out an EIDL for payroll costs or otherwise between January 31, 2020, and the date Paycheck Protection Loans are first made available may be able to refinance its EIDL through the Paycheck Protection Program
- **Special Note - Affiliation Rules**: Standard SBA Affiliation rules currently apply to venture backed companies looking to obtain a PPP loan (affiliation rule details can be found [here](#) and [here](#))
- A company may be considered an “affiliate” of an investor if that investor either (a) maintains majority ownership (multiple definitions), or (b) is deemed to have “control” over the governing board or the operations of the company
- If a company is deemed to be an “affiliate” of one or more of its investors, then the employees of the affiliated investor(s) and potentially the employees of the investor’s other portfolio companies will be included in the total employee count that is used to determine eligibility for the PPP loan
- The company will be ineligible for the PPP loan if the total amount of affiliated employees exceeds 500
- **Note**: The NVCA and other national organizations are currently working with lawmakers to relax the application of the current SBA affiliation rules for loans made under the PPP
- **Mainstreet Lending Program - \$75B** (policy enacted 4/9/20)
  - Federal Reserve announced two facilities to support up to \$600B of lending to small and mid-sized businesses
  - The program will utilize \$75B of capital made available from the U.S. Department of the Treasury using funds appropriated by the CARES Act. When leveraged by the Federal Reserve, this will provide up to \$600B in liquidity for participating lenders
  - This program intends to support mid-size businesses (greater than 500 employees) that were previously ineligible for loan funding under previously approved CARES financial stimulus programs
  - All loans issued under the program will have an interest rate equal to 2.0%-4.0% + SOFR, a four-year maturity, and a minimum loan size of \$1M
  - **New Loan Facilities**: Borrowers trying to obtain a new loan facility will be subject to the lesser of (i) \$25M and (ii) an amount that, when

	<p>added to the existing outstanding and committed but undrawn debt, does not exceed 4.0x 2019 EBITDA</p> <ul style="list-style-type: none"> <li>○ <u>Expanded Loan Facilities</u>: Borrowers will be subject to the lesser (i) \$150M, (ii) 30% of the existing outstanding and committed but undrawn bank debt and (iii) an amount that does not exceed 6.0x 2019 EBITDA, including existing and committed and undrawn debt</li> </ul> <ul style="list-style-type: none"> <li>● <b>Social Security Payroll Tax Deferment</b> <ul style="list-style-type: none"> <li>○ Businesses can defer Social Security payroll taxes for the remainder of 2020, instead paying 50% in 2021 and 50% in 2022</li> <li>○ This deferment is being made available to businesses immediately</li> <li>○ <b>Warning:</b> Deferral is not allowed for companies that receive forgiveness of debt under the PPP</li> </ul> </li> <li>● <b>Employee Retention Tax Credit (SSI Tax Credit)</b> <ul style="list-style-type: none"> <li>○ Employers may be eligible for a refundable tax credit for their share of the 6.2% Social Security tax</li> <li>○ The refundable credit is available for 50% of the first \$10,000 in qualified wages (including health plan expenses) paid to each employee</li> <li>○ Paid sick and paid family and medical leave paid out as part of the FFRCA do not count as qualified wages</li> <li>○ For employers with <u>more than 100 employees</u>, only wages paid to employees who are not working count toward the credit</li> <li>○ For employers with <u>less than 100 employees</u>, all paid wages count toward the credit</li> <li>○ To be eligible, an employer must: <ul style="list-style-type: none"> <li>▪ (1) Have had operations fully or partially suspended because of a shut-down order from a governmental authority related to COVID-19, <b>or</b></li> <li>▪ (2) Have had gross receipts decline by more than 50% in a quarter when compared to the same quarter in 2019</li> </ul> </li> <li>○ The employer will remain eligible for the credit for the remainder of 2020 as long as gross receipts in a quarter do not exceed 80% of gross receipts in the same quarter in 2019</li> <li>○ <b>Warning:</b> The SSI Tax Credit is not available if an employer receives a covered loan from the SBA (e.g., a loan provided through the PPP)</li> </ul> </li> <li>● <b>Additional Tax Relief for Businesses</b> <ul style="list-style-type: none"> <li>○ <b>Net Operating Losses (NOLs):</b> NOLs generated in 2018, 2019, or 2020 may now be carried back up to five years; businesses are allowed to file amended returns to carryback NOLs and generate an immediate return, if applicable</li> <li>○ <b>Note:</b> See <a href="#">National Law Review</a> summary for a full breakdown</li> </ul> </li> </ul>
<p><b>Healthcare Implications</b></p>	<p><b>TELEHEALTH</b></p> <ul style="list-style-type: none"> <li>● <b>“Originating Site” Rule:</b> Medicare beneficiaries in both rural and non-rural areas can now receive covered telehealth services even if they are not physically located in a designated medical facility (e.g., if they are in their place of residence)</li> </ul>



- **Pre-Existing Relationship Requirement:** Medicare beneficiaries will be reimbursed for telehealth services even if they do not have a pre-existing relationship with a physician who provided the care
- **Reimbursement for Providers in Rural and Underserved Areas:** Providers at rural health clinics and federally qualified health centers can now be reimbursed for telehealth services at rates comparable to the national average
- **Telehealth Network and Telehealth Resource Centers (TRCs) Grant Programs:** Reauthorizes the HRSA TRC Grant programs
- **Health Savings Accounts:** Allows a high-deductible health plan (HDHP) with a health savings account (HSA) to cover telehealth services prior to a patient reaching the deductible
- **Medicare Telehealth Flexibility:** Removes the COVID-19 Medicare telehealth waiver requirement that a provider must have seen the patient within the last 3 years, gives flexibility to providers to offer audio-only telehealth, and provides the Secretary of HHS with expanded authority to waive statutory restrictions on Medicare telehealth services
- **Federally Qualified Health Centers and Rural Health Clinics:** Allows Federally Qualified Health Centers and Rural Health Clinics to serve as distant sites for telehealth during the COVID-19 emergency period
- **Home Dialysis Patients:** Eliminates a requirement that a nephrologist conduct a portion of required periodic home dialysis evaluations face-to-face
- **Hospice Care Certification Requirement:** Allows qualified providers to use telehealth in order to fulfill the hospice face-to-face recertification requirement during the COVID-19 emergency period
- **FCC Allowance:** Provides \$200 million for the Federal Communications Commission (FCC) to support the efforts of health care providers by providing telecom services, information services, and devices necessary to enable the provision of telehealth services
- **VA Medical Services:** Provides \$14.4 billion to support increased demand for healthcare services at VA facilities and through telehealth
- **VA IT Services:** Provides \$2.15 billion to support increased telework, telehealth, and call center capabilities
- **VA Telehealth Expansion:** Authorizes the VA to expand mental health services delivered via telehealth and enter into short-term agreements with telecom companies to provide veterans with temporary broadband services
- **VA Veteran Direct Care Program:** Waives the in-person home visit requirement to enroll patients and permits telephone and telehealth visits as an alternative
- **VA Case Managers and Homeless Veterans:** Ensures telehealth capabilities are available for case managers and homeless veterans participating in the HUD–VASH program

#### MEDICARE

- **Inpatient Add-on Payment for COVID–19 Patients:** A new add-on payment will be made for each Medicare inpatient hospital discharged with a COVID-19 diagnosis. The add-on payment increases weighting factors for the DRG assigned to the discharged patient by 20%

- **Accelerated Payments:** Expands the CMS accelerated payment policy by (1) increasing the prepayment amount, (2) increasing the length of time accelerated payments may cover, (3) delaying the start of recoupment of any overpayments, (4) extending the due date for any outstanding balances, and (5) expanding the types of hospitals (including critical access, children’s and cancer hospitals) that are eligible to apply for accelerated payments
- **Suspension of Policies that Reduce Payments:** Temporarily suspends (1) the 2% Medicare sequestration, (2) site-neutral policy that subjects a portion of long-term care hospital (LTCH) stays to lower rates, and (3) revisions to the Medicare durable medical equipment payment methodology
- **Home Health Services:** The HHS Secretary will put forth regulation permitting nurse practitioners, clinical nurse specialists, and physician assistants working in accordance with state law to order Medicare home health services; states will be required to make similar changes for Medicaid
- **Increasing Access to Post-acute Care:** Temporarily relaxes some Medicare requirements applicable to inpatient rehabilitation facilities (IRFs) and long-term care hospitals (LTCHs) during the COVID-19 emergency. Waivers include: a temporary waiver of the IRF 3-hour rule, a temporary waiver of “50 percent rule” payment reductions for LTCHs, and a temporary waiver of site-neutral payment reduction for LTCHs
- **Reporting Requirements for Clinical Diagnostic Lab Tests:** Delays the date on which clinical laboratory tests must report private sector payment rates from January 1, 2021 to January 1, 2022, and extends the phase-in of planned Medicare payment reductions that are based on such private payer rate information
- **Coverage of COVID-19 Vaccine(s):** Adds COVID-19 vaccines and its administration to the definition of medical and other health services covered under Medicare Part B and ensures that such vaccine will be covered without any cost-sharing; the same coverage has been added to Medicare Advantage plans
- **Part D Prescriptions and Refills:** Requires Part D prescription drug plans and Medicare Advantage prescription drug (MA-PD) plans to allow enrollees to obtain up to a 90-day supply of a prescribed and covered Part D drug

#### MEDICAID

- **Extending Payment to Acute Care Hospitals for Home and Community-based Services (HCBS):** Ensures that federal Medicaid matching funds are available to state Medicaid programs for (1) certain HCBS services that may be covered as part of a state plan amendment or waiver and (2) self-directed personal assistance services
- **Delaying Requirements for Enhanced Federal Medical Assistance Percentage (FMAP):** Amends a provision in the FFCRA so that states may qualify for a 6.2% increase in FMAP for 30 days after the enactment of the CARES Act, if they have increased premiums in 2020. States will need to decrease premiums to January 1, 2020 levels if they seek to continue receiving the increase in FMAP after the 30 days have elapsed.
- **Medicaid Coverage of COVID-19 Testing Products:** Expands the definition of “uninsured individuals” who are eligible for testing services with no cost

	<p>sharing to include certain categories of individuals, such as individuals eligible for (but not enrolled in) federal health care programs who do not have minimum essential coverage</p> <ul style="list-style-type: none"> <li>• <b>Disproportionate Share Payments:</b> Delays scheduled reductions in Medicaid disproportionate share hospital payments through November 30, 2020</li> <li>• <b>Community Mental Health:</b> Extends the Medicaid Community Mental Health Services demonstration that provides coordinated care to patients with mental health and substance use disorders through November 30, 2020</li> </ul> <p><b>SUPPLEMENTAL MEDICAL APPROPRIATIONS - \$330B</b></p> <ul style="list-style-type: none"> <li>• Allocates funds for healthcare related programs and services to: <ul style="list-style-type: none"> <li>○ Provide grants to hospitals, public entities, not-for-profit entities, and Medicare and Medicaid enrolled suppliers and institutional providers to cover unreimbursed healthcare related expenses or lost revenues attributable to the COVID-19 emergency</li> <li>○ Replenish the Strategic National Stockpile supplies of pharmaceuticals, PPE, and other medical supplies</li> <li>○ Support R&amp;D of vaccines, therapeutics, and diagnostics to prevent or treat the effects of coronavirus</li> <li>○ Support domestic supply chains, enabling industry to quickly increase production of PPE, ventilators, and other supplies for federal, state, and local public health agencies to respond to COVID-19</li> <li>○ Support rural critical access hospitals, rural tribal health and telehealth programs</li> </ul> </li> </ul>
<p><b>Digital Health Startup Implications</b></p>	<ul style="list-style-type: none"> <li>• Many early stage companies will be deemed eligible to apply for financial stimulus resources, such as a <a href="#">PPP loan</a>, so long as they meet the affiliation requirements (See Action Items)</li> <li>• Lenders are expected to review and approve loan application on rolling basis (i.e., first come, first serve in most cases), so startups should submit applications as soon as possible</li> <li>• Companies offering or considering offering <a href="#">telemedicine</a> may be positively impacted by the loosened regulatory restrictions such as the originating site rule, preexisting relationship, or CMS reimbursement flexibilities</li> </ul>
<p><b>Action Items</b></p>	<ul style="list-style-type: none"> <li>• Work with your accountant and legal advisors to determine loan options (<b>Note:</b> EDILs have stricter underwriting requirements than <a href="#">PPP loans</a> and the debt is not forgivable)</li> <li>• Determine your plans for applying for a loan and understand the limitations and trade-offs involved when taking advantage of the loan option versus the tax refund and deferral offerings; in most cases the value of the loan will exceed the tax benefits of the other two options</li> <li>• Determine if SBA affiliation rules are applicable to your employee count and work to understand if this may impact your <a href="#">PPP loan</a> eligibility</li> <li>• Immediately begin preparing financial documentation for the PPP loan application and initiate discussions with your preferred bank or lender (<b>Note:</b> <a href="#">SBA lender list</a>; also, the Federal Reserve and SBA have indicated that they will work with additional interested and credible lenders to expedite their ability to participate in the program) <ul style="list-style-type: none"> <li>○ Documents to compile include:</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>▪ Payroll components and other qualifying expenses broken out by month for 2019</li> <li>▪ Audited financial statements (past 3 years if available)</li> <li>▪ Tax filings (past 3 years if available)</li> <li>▪ Cap table</li> <li>▪ Governance and bylaw documentation</li> </ul>
<b>Sources</b>	<ul style="list-style-type: none"> <li>• <a href="#">National Law Review Summary</a></li> <li>• <a href="#">Foley &amp; Lardner</a></li> <li>• <a href="#">SBA Affiliation Guidelines</a></li> <li>• <a href="#">Hogan Lovells</a></li> <li>• <a href="#">American Telemedicine Association</a></li> <li>• <a href="#">CARES Act (PDF Text)</a></li> <li>• <a href="#">Tax Relief Components</a></li> <li>• <a href="#">Federal Reserve Press Release Mainstreet Lending Program</a></li> </ul>

### III. CMS COVID-19 Emergency Declaration Waivers & Flexibilities for Health Care Providers

The Secretary of the Department of Health and Human Services (HHS) has used section 1135 of the Social Security Act to modify or waive certain Medicare, Medicaid, CHIP, or HIPAA requirements, called 1135 waivers, including Medicare blanket waivers. When a blanket waiver is issued, providers don't have to apply for an individual 1135 waiver.

In addition to the blanket waivers outlined below, 40 states have approved coronavirus 1135 waivers.

#### a. Specific Waivers & Potential Implications for 7Wire Portfolio Companies

Specific Blanket Waivers & Potential Implications for 7wire Portfolio Companies	
Impacted Stakeholder / Area	Policy & Waiver
<b>Telemedicine Waivers</b>	<ul style="list-style-type: none"> <li>• Rural and site limitations are removed. Telehealth services can now be provided regardless of where the enrollee is located geographically and by site, which allows allowing a patient's home to be an eligible originating site</li> <li>• Telehealth visits are considered the same as in-person visits and are paid at the same rate as regular, in-person visits</li> <li>• HHS Office of Inspector General (OIG) is providing flexibility for healthcare providers to reduce or waive cost-sharing for telehealth visits paid by federal healthcare programs</li> </ul>

	<ul style="list-style-type: none"> <li>• CMS is waiving the requirement for providers to have a valid license for the state in which they provide care for Medicare patients; states may request similar waivers for Medicaid patients</li> <li>• CMS has expanded the list of acceptable platforms upon which telehealth services may be provided</li> <li>• HHS will not conduct audits to track whether there was a prior patient-physician relationship for telehealth claims submitted during the public health emergency</li> <li>• Patients must still initiate services, but physicians may inform their patients on the availability of telehealth services</li> <li>• The OCR will exercise enforcement discretion for HIPAA laws and will not impose penalties for noncompliance with regulatory requirements during the good faith provision of telehealth services (e.g. Zoom or Facetime based telemedicine calls)</li> <li>• Medicare Advantage (MA) plans have the flexibility to have more expansive telehealth policies related to types of services covered, where those services can take place (no geographic or site limitations), and modality used</li> <li>• CMS will exercise enforcement discretion if MA plans wish to expand coverage of telehealth services beyond what has been approved</li> <li>• [See Hospice, CAH/LTCH, and ESRD sections for additional details on specific telemedicine waivers]</li> </ul>
<p><b>Digital Health Startup Implications</b></p>	<ul style="list-style-type: none"> <li>• Startup companies can provide expanded access to telehealth services for Medicare consumers due to lifted restrictions on devices, geographies, locations, and prior patient/physician relationships: <ul style="list-style-type: none"> <li>○ Services can be offered via telephone, smart phone applications, or laptops directly to patients in their homes regardless of geographic location <ul style="list-style-type: none"> <li>▪ Approved platforms include Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, and Skype</li> <li>▪ Public facing video communication apps, such as Facebook Live, Twitch, and TikTok, are not approved</li> </ul> </li> <li>○ Startup companies can virtually service geographies with providers licensed in a separate state for Medicare and in some cases Medicaid as well</li> <li>○ Startup companies can provide telehealth services without demonstrating prior patient-physician relationships</li> </ul> </li> <li>• Startup companies can aid the expansion of the health care workforce by allowing clinicians to deliver care virtually <ul style="list-style-type: none"> <li>○ Startup companies can virtually service geographies with providers licensed in a separate state for Medicare and in some cases Medicaid</li> <li>○ Self-quarantined or part-time clinicians can be employed to deliver care virtually</li> </ul> </li> </ul>

- Health systems can provide care based on population management strategies, such as triaging by COVID-19 and clinical status, to better manage patient volumes
- Startup companies can help put patients over paperwork by using digital health solutions to reduce administrative burdens and triage patients as needed
  - Extension of audit and quality reporting deadlines and suspension of medical necessity documentation, such as prior authorizations

b. Summary & Detailed information for all Blanket Waivers

[COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers](#)

Effective retroactively as of 3/1/2020 through the end of the emergency declaration

High Level Summary of Blanket Waivers	
Impacted Stakeholder / Area	Policy & Waiver
<b>Telehealth</b>	People with Medicare can now receive telehealth services from their home, increasing their access to care
<b>Care by Phone</b>	Patients can consult with a doctor, nurse practitioner, psychologist, and others by phone and will be covered by Medicare
<b>Rapidly Expand Health Care Workforce</b>	A physician who has to self-quarantine can be recruited to provide care virtually, or oversee care delivered by other clinicians through interactive video/audio conferencing. Medicare will pay for providers who are licensed in one state to provide care in a different state if they are needed. Health systems can provide care options that use population management strategies like triaging based on COVID status as well as clinical status, employing doctors, nurses, and other staff to better manage high patient volumes. Clinicians who are not fully employed during the emergency can be repurposed to provide care in other areas.
<b>Testing Patients Where They Are</b>	Physician-ordered lab tests for COVID-19 can be accessed by individuals at a drive-up testing center. A laboratory may be able to send representatives to an individual's home to collect test samples.
<b>Making the Most Use of Community Health Care Resources</b>	Hospitals can transfer patients to different types of units and facilities to keep patients safe and expand bed capacity
<b>COVID-only Care Centers</b>	During the public health emergency, hospitals and dialysis centers can set up COVID-only centers to help reduce transmission to others
<b>Expanding Hospital Capacity</b>	Community resources such as hotels, convention centers, and surgery centers can be converted for hospital care
<b>Patients Over Paperwork</b>	Administrative burdens have been reduced dramatically. Frontline providers are permitted to triage patients and coordinate care despite high volume and extraordinary system stresses. By extending quality reporting deadlines and suspending medical necessity documentation, CMS aims to give time back to doctors so they can focus on their patients. For example, provider documentation requirements for prior authorization are temporarily suspended. Additionally, CMS has made regulatory changes to provide temporary relief from many audit and quality reporting requirements so that providers, healthcare facilities, Medicare Advantage health plans, Part D prescription drug plans, and states can focus on providing needed care to Medicare and Medicaid beneficiaries affected by COVID-19.

## Detailed Information on Blanket Waivers

### Listed by Impacted Stakeholder / Area:

- Hospitals, Psychiatric Hospitals, and Critical Access Hospitals (CAHs), including Cancer Centers and Long-Term Care Hospitals (LTCHs)
- Relocation of Patients
- Payment Requirements
- Long-Term Care Facilities and Skilled Nursing Facilities (SNFs) and/or Nursing Facilities
- Home Health Agencies (HHA)
- Hospice
- End-Stage Renal Dialysis (ESRD) Facilities
- Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)
- Practitioner Locations & Licensing
- Provider Enrollment to Temporarily Receive Medicare Billing Privileges
- Medicare Appeals in Fee for Service (FFS), Medicare Advantage (MA) and Part D
- Medicaid and CHIP (as of 3/13/2020)
- Stark Law
- Additional Clarification on Waivers Granted Under Section 1135 of the Social Security Act

Impacted Stakeholder / Area	Policy & Waiver
<b>Hospitals, Psychiatric Hospitals, and Critical Access Hospitals (CAHs), including Cancer Centers and Long-Term Care Hospitals (LTCHs)</b>	<ul style="list-style-type: none"> <li>• <b>Emergency Medical Treatment &amp; Labor Act</b> – allowing screening of patients at a location offsite from hospital’s campus to prevent spread</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Verbal Orders</b> – waiving requirements for verbal orders where readback verification is required but authentication may occur later than 48 hours to allow more efficient treatment in surge situations</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Reporting Requirements</b> – waiving requirements for reporting of patients in an ICU whose death is caused by their disease but who required soft wrist restraints to prevent pulling tubes/IVs by close of business on the next business day</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Patient Rights</b> – <i>only for hospitals considered impacted by a widespread outbreak of COVID-19</i> – waiving requirements to abide by timeframes in providing a copy of a medical record, have written policies and procedures on visitation of patients in COVID-19 isolation and quarantine, and regarding seclusion</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Sterile Compounding</b> – allowing used face masks to be removed and retained in the compounding area to be re-donned and reused during the same work shift in the compounding area only to conserve supplies</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Detailed Information Sharing for Discharge Planning for Hospitals and CAHs</b> – waiving requirements to provide detailed information on discharge planning, such as assisting in selection of post-acute care providers</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Limited Detailed Discharge Planning for Hospitals</b> – waiving detailed requirements related to information in discharge plans to post-acute</li> </ul>



<p><b>Hospitals, Psychiatric Hospitals, and Critical Access Hospitals (CAHs), including Cancer Centers and Long-Term Care Hospitals (LTCHs)</b> continued</p>	<p>care services to expedite safe discharge and movement of patients among care settings</p>
	<ul style="list-style-type: none"> <li>• <b>Medical Staff</b> – allowing physicians whose privileges will expire to continue practicing at the hospital and for new physicians to practice before full medical staff/governing body review and approval</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Medical Records</b> – waiving requirements around organization and staffing of medical records department, form and content of the medical record, and record retention; allowing completion of records within 30 days following hospital discharge</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Flexibility in Patient Self Determination Act Requirements (Advance Directives)</b> – waiving Medicaid, Medicare, and Medicare Advantage requirements that require providers to inform patients of their advance directive policies</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Physical Environment</b> – allowing non-hospital buildings/space to be used for patient care and quarantine sites under Medicare conditions, provided the location is approved by the state</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Telemedicine</b> – waiving provisions related to telemedicine to make it easier for telemedicine services to be furnished through an agreement with an off-site hospital</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Physician Services</b> – waiving requirements that Medicare patients be under the care of a physician</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Anesthesia Services</b> – waiving requirements that a certified registered nurse anesthetist is under the supervision of a physician; supervision will be at the discretion of the hospital and state law</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Utilization Review</b> - waiving certain requirements to address the statutory basis for hospitals, including that hospitals participating in Medicare and Medicaid must have a utilization review plan that meets specified requirements; waiving the entire utilization review condition requiring a committee to evaluate medical necessity of admission, duration of stay, and services provided</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Written Policies and Procedures for Appraisal of Emergencies at Off Campus Hospital Departments</b> – waiving requirement of written policies and procedures for staff to use when evaluating emergencies for surge facilities only</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Emergency Preparedness Policies and Procedures</b> – waiving requirements to develop and implement emergency preparedness policies and procedures and to include specified elements in communication plans such as staff contact information with respect to surge sites</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Quality Assessment and Performance Improvement Program</b> – waiving requirement to provide details on scope of programs, incorporation, and setting priorities for program’s performance improvement activities; ongoing data-driven quality assessment and performance improvement program requirements remain</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Nursing Services</b> – waiving requirements for nursing staff to develop and keep current nursing care plans for each patient and for hospitals to have policies and procedures in place establishing which</li> </ul>

	<p>outpatient departments are not required to have a registered nurse present</p> <ul style="list-style-type: none"> <li>• <b>Food and Dietetic Services</b> – waiving requirement for providers to have a current therapeutic diet manual approved by the dietitian and medical staff readily available to all medical, nursing, and food service personnel; manuals do not need to be maintained at surge capacity sites</li> <li>• <b>Respiratory Care Services</b> – waiving requirement for hospitals to designate in writing the personnel qualified to perform specific respiratory care procedures and the amount of supervision required for personnel to carry out specific procedures</li> <li>• <b>CAH Personnel Qualifications</b> – waiving minimum personnel qualifications for clinical nurse specialists, nurse practitioners, and physician assistants so that CAHs can employ individuals who meet state licensure requirements</li> <li>• <b>CAH Staff Licensure</b> – deferral of staff licensure, certification, or registration to state law by waiving federal requirements</li> <li>• <b>CAH Status and Location</b> – waiving the requirement that the CAH be located in a rural area or an area being treated as rural for flexibility of surge site locations; also waiving the requirements of off-campus and co-location requirements to establish temporary off-site locations</li> <li>• <b>CAH Length of Stay</b> – waiving Medicare requirements that CAHs are limited to 25 beds and 96 hours for length of stay</li> <li>• <b>Temporary Expansion Locations</b> – allowing hospitals under Medicare conditions to change the status of their current provider-based department locations as needed to address the needs of hospital patients as part of the state or local pandemic plan, including current hospitals establishing new locations or ambulatory surgical centers enrolling as hospitals during the public health emergency</li> </ul>
<p><b>Relocation of Patients</b></p>	<ul style="list-style-type: none"> <li>• <b>Housing Acute Care Patients in the IRF or Inpatient Psychiatric Facility (IPF) Excluded Distinct Part Units</b> – Allowing acute care hospitals to house acute care inpatients in excluded distinct part unit IRFs or IPFs where appropriate; Inpatient Prospective Payment System hospital should bill for care and annotate the patient’s medical record</li> <li>• <b>Care for Excluded Inpatient Psychiatric Unit Patients in the Acute Care Unit of a Hospital</b> – Allowing acute care hospitals with excluded distinct part inpatient psychiatric units to relocate inpatients to an acute care bed and unit when deemed safe after assessment as a result of disaster or emergency; continue billing for inpatient psychiatric services and annotate the medical record</li> <li>• <b>Care for Excluded Inpatient Rehab Unit Patients in the Acute Care Unit of a Hospital</b> – Allowing acute care hospitals with excluded distinct part inpatient rehab units to relocate patients to an acute care bed as a result of disaster or emergency; continue billing for inpatient rehab services and annotate the medical record</li> </ul>

<b>Payment Requirements</b>	<ul style="list-style-type: none"> <li>• <b>Flexibility for Inpatient Rehab Facilities Regarding the “60 Percent Rule”</b> – Allowing IRFs and facilities attempting to obtain classification as an IRF to exclude patients from freestanding hospital or excluded distinct part unit patient populations to calculate applicable thresholds associated with payment requirements if a patient admitted solely to respond to the emergency</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Extension for Inpatient Prospective Payment System (IPPS) Wage Index Occupational Mix Survey Submission</b> – Granting an extension until August 3, 2020, for acute care hospitals participating in Medicare that are affected by COVID-19 to submit occupational mix of employees; extensions may be considered if concerns are communicated</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Supporting Care for Patients in Long-Term Acute Care Hospitals (LTCHs)</b> - Allowing LTCH to exclude patient stays where patient is admitted or discharged to meet the demands of the emergency from the 25-day average length of stay requirement for payment</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Care for Patients in Extended Neoplastic Disease Care Hospitals</b> – allowing extended neoplastic disease care hospitals to exclude inpatient stays where hospital admits or discharges patients to meet the demands of the emergency from the greater than 20-day average length of stay requirement</li> </ul>
<b>Long-Term Care Facilities and Skilled Nursing Facilities (SNFs) and/or Nursing Facilities</b>	<ul style="list-style-type: none"> <li>• <b>3-Day Prior Hospitalization</b> – waiving the requirement for a 3-day prior hospitalization for coverage of a SNF stay; additionally, allowing renewed SNF coverage for beneficiaries who have exhausted benefits without having to start a new benefit period (only applicable to those delayed or prevented from doing so by the emergency)</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Reporting Minimum Data Set</b> – waiving requirements for Minimum Data Set assessments and transmission</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Staffing Data Submission</b> – waiving requirements for submitting staffing data through the Payroll-Based Journal System</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Waive Pre-Admission Screening and Annual Resident Review (PASARR)</b> – allowing states and nursing homes to suspend assessments for new residents for 30 days; after 30 days, new patients admitted with mental illness or intellectual disability should be assessed as soon as resources are available</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Physical Environment</b> – allowing non-SNF buildings to be temporarily certified and available for isolation processes to protect vulnerable adults; waiving certain participation and certification requirements for opening a NF; allowing use of rooms in a long-term care facility not normally used as a resident’s room to accommodate beds and residents in emergencies and surge situations</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Resident Groups</b> – waiving requirements to ensure residents can participate in-person in resident groups</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Training and Certification of Nurse Aides</b> – waiving requirements that a SNF and NF may not employ anyone more than 4 months without meeting training and certification requirements; facilities still may not use nurse aides for more than 4 months full-time without</li> </ul>

	<p>demonstrating competency to provide nursing and nursing related services through resident assessments and described in the care plan</p>
	<ul style="list-style-type: none"> <li>• <b>Physician Visits in Skilled Nursing Facilities/Nursing Facilities</b> – allowing visits for nursing home residents via telehealth</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Resident roommates and grouping</b> – grouping residents with respiratory symptoms and/or residents with a confirmed diagnosis of COVID-19 and separating them from asymptomatic or negative-testing patients; waiving requirements to allow a resident to share a room, provide notice for room changes, and transfers upon refusal</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Resident transfer and discharge</b> – allowing LTC facilities to transfer or discharge residents to other LTC facilities or COVID-19 isolation/treatment facilities for cohort purposes, including transferring residents with symptoms or confirmed diagnosis, transferring residents without symptoms or confirmed diagnosis, or transferring residents without symptoms to observe <ul style="list-style-type: none"> <li>○ <b>Exception:</b> requirements are only waived when the transferring facility receives confirmation of acceptance from the receiving facility; verbal confirmations must have date, time, and person documented</li> <li>○ <b>Exception:</b> only waiving the requirement that a facility provide advance notification of options relating to transfer or discharge</li> <li>○ <b>Exception:</b> only waiving timeframes for certain care planning requirements who are transferred or discharged for the stated reasons; receiving facilities should complete required care plans as soon as practicable</li> <li>○ <b>Exception:</b> if transfer is inconsistent with a state’s emergency preparedness or pandemic plan <ul style="list-style-type: none"> <li>▪ Provision of services should be “under arrangement” where the transferring facility bills Medicare and then reimburses the treatment facility; otherwise the treatment facility is responsible for Medicare billing</li> </ul> </li> </ul> </li> </ul>
<p><b>Home Health Agencies (HHAs)</b></p>	<ul style="list-style-type: none"> <li>• <b>Requests for Anticipated Payment (RAPs)</b> – allowing Medicare Administrative Contractors to extend auto-cancellation date of Requests for Anticipated Payment during emergencies</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Reporting</b> – relief to HHAs on timeframes related to OASIS Transmission by extending the 5-day completion requirement for comprehensive assessment to 30 days and waiving the 30-day submission requirement to permit delays</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Initial Assessments</b> – allowing HHAs to perform Medicare-covered initial assessments and determine patients’ homebound status remotely or by record review</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Waive onsite visits for HHA Aide Supervision</b> – waiving requirements for a nurse to conduct an onsite visit every two weeks, including to evaluate if aides are providing care consistent with the care plan; suspending two-week aide supervision by a registered nurse although virtual supervision is encouraged</li> </ul>

<p><b>Hospice</b></p>	<ul style="list-style-type: none"> <li>• <b>Waive Requirement for Hospices to Use Volunteers</b> – waiving the requirement to use volunteers, including at least 5% of patient care hours</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Comprehensive Assessments</b> – waiving certain requirements to update comprehensive patient assessments, extending timeframes for updates from 15 to 21 days</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Waive Non-Core Services</b> – waiving the requirement to provide certain non-core hospice services, including physical therapy, occupational therapy, and speech-language pathology</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Waived Onsite Visits for Hospice Aide Supervision</b> – waiving the requirements for a nurse to conduct an onsite supervisory visit every two weeks, including to evaluate if aides are providing care consistent with the care plan</li> </ul>
<p><b>End-Stage Renal Dialysis (ESRD) Facilities</b></p>	<ul style="list-style-type: none"> <li>• <b>Training Program and Periodic Audits</b> – CMS is waiving the requirement for on-time periodic audits for operators of water/dialysate equipment is waived to allow for flexibility</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Defer Equipment Maintenance &amp; Fire Safety Inspections</b> – CMS is waiving the requirement for on-time preventive maintenance of dialysis machines and ancillary dialysis equipment and the requirement for ESRD facilities to conduct on-time fire inspection</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Emergency Preparedness</b> – CMS is waiving the requirement for maintenance of CPR certification and requirements for ESRD facilities to demonstrate that patient care staff maintains CPR certification</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Patient Assessments</b> – CMS is waiving 42 CFR §494.80(b), specifically, the requirements that an initial comprehensive assessment be performed on all new patients (i.e., all admissions to a dialysis facility), within the latter of 30 calendar days or 13 outpatient hemodialysis sessions, and that a follow up comprehensive reassessment must occur within 3 months of the initial assessment</li> <li>• <b>Note:</b> CMS is <u>not</u> waiving subsections (a) or (c) of 42 CFR §494.80</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Care Planning and Monthly Physician Visits</b> – CMS is modifying the requirement that a dialysis facility implements an initial plan of care within 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions, as well as the requirement for monthly or annual updates of the plan of care within 15 days of additional patient assessments (see CMS website for details)</li> <li>• CMS is also waiving the requirement for a monthly in-person visit if the patient is considered stable</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Dialysis Home Visits to Assess Adaptation</b> – CMS is waiving the requirement for periodic monitoring of a patient’s home adaptation, including visits to the patient’s home by facility personnel</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Special Purpose Renal Dialysis Facilities (SPRDF) Designation</b> - CMS has authorized the establishment of SPRDFs under 42 CFR §494.120 to address access to care issues due to COVID-19; approval as a Special Purpose Renal Dialysis Facility related to COVID-19 does not require Federal survey prior to providing services</li> </ul>

	<ul style="list-style-type: none"> <li>• <b>Dialysis Patient Care Technician (PCT) Certification</b> - CMS will allow PCTs to continue working even if they have not achieved certification within 18 months or have not met on-time renewals</li> <li>• <b>Transferability of Physician Credentialing</b> – CMS will allow physicians that are appropriately credentialed at a certified dialysis facility to function to the fullest extent of their licensure at designated isolation locations without separate credentialing at that facility, as long as this is not inconsistent with a state’s emergency preparedness or pandemic plan</li> <li>• <b>Expanding availability of ESRD to Nursing Home Residents</b> – CMS is allowing dialysis facilities to provide service to its patients in a nursing home or skilled nursing facility; services provided to these nursing home residents must be provided under the direction of the same governing body and professional staff as the resident’s usual Medicare-certified dialysis facility</li> <li>• <b>Note:</b> Dialysis facility staff must furnish all dialysis care and services, provide all equipment and supplies, and complete all requisite equipment maintenance, cleaning and disinfection</li> <li>• <b>Note:</b> The dialysis center should bill Medicare using Condition Code 71 (i.e., Billing for a patient who received staff-assisted dialysis services in a hospital or renal dialysis facility)</li> </ul>
<p><b>Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)</b></p>	<ul style="list-style-type: none"> <li>• <b>DMEPOS Replacement</b> – Durable Medical Equipment Medicare Administrative Contractors now have the flexibility to waive replacement requirements; the face-to-face requirement, a new physician’s order, and new medical necessity documentation are no longer required as long as appropriate documentation is maintained</li> </ul>
<p><b>Practitioner Locations and Licensing</b></p>	<ul style="list-style-type: none"> <li>• <b>Licensing Requirements</b> - CMS is temporarily waiving requirements that out-of-state practitioners be licensed in the state where they are providing services if they are licensed in another state</li> <li>• Four conditions must be met for practitioners to qualify: <ul style="list-style-type: none"> <li>○ Must be enrolled in the Medicare program</li> <li>○ Must possess a valid license to practice in the state which relates to his or her Medicare enrollment</li> <li>○ Must be furnishing services – in person or via telehealth – in a state in which the emergency is occurring in order to contribute to relief efforts in his or her professional capacity</li> <li>○ Must not be affirmatively excluded from practice in the state or any other state that is part of the 1135 emergency area</li> </ul> </li> <li>• <b>Note:</b> In order for a practitioner to avail themselves of this 1135 waiver, the state must also waive its licensure requirements; this CMS waiver does not waive state or local licensure requirements</li> </ul>
<p><b>Provider Enrollment to Temporarily Receive Medicare Billing Privileges</b></p>	<ul style="list-style-type: none"> <li>• <b>Screening Requirements</b> – CMS is waiving several Medicare billing enrollment requirements: application fees, fingerprint based criminal background checks, and site visits (all to the extent applicable)</li> <li>• <b>Extensions, Postponements, and Allowances</b> – CMS will also postpone all revalidation actions, expedite any pending or new applications, allow licensed providers to render services outside of</li> </ul>

	<p>their state of enrollment, allow physicians and other practitioners to render and bill for telehealth services from their home, and allow opted-out practitioners to terminate their opt-out status early</p>
<p><b>Medicare Appeals in Fee for Service (FFS), Medicare Advantage (MA) and Part D</b></p>	<ul style="list-style-type: none"> <li>• <b>Medicare Appeals Process</b> - CMS is allowing MACs and QICs in the FFS program 42 CFR 405. 950 and 42 CFR 405.966 and MA and Part D plans, as well as the Part C and Part D IREs to do the following: <ul style="list-style-type: none"> <li>○ Allow extensions to file an appeal</li> <li>○ Waive requirements for timeliness for requests for additional information to adjudicate appeals</li> <li>○ Process an appeal even with incomplete Appointment of Representation forms</li> <li>○ Process requests for appeal that don't meet the required elements using information that is available</li> <li>○ Utilize all flexibilities available in the appeal process as if good cause requirements are satisfied</li> </ul> </li> </ul>
<p><b>Medicaid and CHIP (as of 3/13/2020)</b></p>	<ul style="list-style-type: none"> <li>• <b>State Waivers</b> - States and territories can request approval for CMS waivers for certain statutes and implementing regulations on a case by case basis; examples of potential waivers include: <ul style="list-style-type: none"> <li>○ Waive prior authorization requirements in FFS programs</li> <li>○ Permit providers located out of state to provide care to another state's Medicaid enrollees impacted by COVID-19</li> <li>○ Temporarily suspend provider enrollment and revalidation requirements to increase access to care</li> <li>○ Temporarily waive requirements that physicians and other health care professionals be licensed in the state in which they are providing services, so long as they have an equivalent licensing in another state</li> <li>○ Temporarily suspend requirements for certain pre-admission and annual screenings for nursing home resident</li> </ul> </li> <li>• More information can be found in the <a href="#">Medicaid disaster response toolkit</a></li> </ul>
<p><b>Stark Law</b></p>	<ul style="list-style-type: none"> <li>• <b>Physician Self-Referral Law ("Stark Law")</b> - CMS issued blanket waivers for certain types of referrals and the submission of related claims that would typically result in sanctions under the physician self-referral law; see the next section of this document for additional details [See details on Pages: 33-35]</li> </ul>
<p><b>Additional Clarification on Waivers Granted Under Section 1135 of the Social Security Act</b></p>	<ul style="list-style-type: none"> <li>• <b>Duration</b> - Waivers under Section 1135 typically end no later than the termination of the emergency period, or 60 days from the date the waiver or modification is first published; the HHS Secretary can extend the waiver by notice for additional periods of up to 60 days, up to the end of the emergency period</li> <li>• <b>Jurisdiction</b> - Waiver authority applies only to Federal requirements and does not apply to State requirements for licensure or conditions of participation</li> </ul>

	<ul style="list-style-type: none"><li>• <b>Blanket Waivers</b> - Once approved, these waivers apply automatically to all applicable providers and suppliers. Providers and suppliers do not need to apply for an individual waiver if a blanket waiver is issued</li><li>• <b>Claims Submission for Blanket Waivers</b> - The “DR” (disaster-related) condition code should be used for institutional billing and the “CR” (catastrophe/disaster-related) modifier should be used for Part B billing, both institutional and non-institutional</li><li>• <b>Provider/Supplier Individual Waivers</b> - Providers and suppliers can submit requests for individual 1135 waivers; the State Survey Agency and CMS Survey Operations Group will review the provider’s request and make appropriate decisions, usually on a case-by-case basis</li></ul>
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c. Blanket Waivers of Section 1877(g) of the Social Security Act – Sanctions under the Physician Self-Referral Law (Stark Law)

[Blanket Waivers of Section 1877\(g\) of the Social Security Act – Sanctions under the Physician Self-Referral Law](#)

These waivers are effective March 1, 2020 and may be used without notifying CMS. Individual waivers of sanctions under section 1877(g) of the Act may be granted upon request. The blanket waivers apply only to financial relationships and referrals related to the national emergency that is the COVID-19 outbreak in the US. Any remuneration described in the blanket waivers must be directly between the entity and (1) the physician or the physician organization in whose shoes the physician stands under or the immediate family member of the physician.

<b>Passed Date</b>	3/30/2020 (effective 3/1/2020)
<b>Goal</b>	<p>To ensure that:</p> <ol style="list-style-type: none"> <li>1. Sufficient health care items and services are available to meet the needs of individuals enrolled in Medicare, Medicaid, and CHIP programs</li> <li>2. Health care providers that furnish such items and services in good faith, but are unable to comply with one or more of the specified requirements of section 1877 of the Act and regulations thereunder as a result of the consequences of the COVID-19 pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent the government’s determination of fraud or abuse</li> </ol>
<b>Blanket Waivers</b>	<ol style="list-style-type: none"> <li>1. <b>Remuneration</b> from an entity to a physician that is above or below the fair market value <b>for services personally performed by the physician to the entity.</b></li> <li>2. <b>Rental charges</b> paid by an entity to a physician that are below fair market value for the entity’s <b>lease of office space from the physician.</b></li> <li>3. <b>Rental charges</b> paid by an entity to a physician that are below fair market value for the entity’s <b>lease of equipment from the physician.</b></li> <li>4. <b>Remuneration</b> from an entity to a physician that is above or below the fair market value <b>for items or services purchased by the entity from the physician.</b></li> <li>5. <b>Rental charges</b> paid by a physician to an entity that are below fair market value for the <b>physician’s lease of office space from the entity.</b></li> <li>6. <b>Rental charges</b> paid by a physician to an entity that are below fair market value for the <b>physician’s lease of equipment from the entity.</b></li> <li>7. <b>Remuneration</b> from a physician to an entity that is below fair market value for the <b>use of the entity’s premises or for items or services purchased by the physician from the entity.</b></li> <li>8. <b>Remuneration from a hospital to a physician in the form of medical staff incidental benefits</b> that exceeds the limits set forth in 42 CFR 411.357(m)(5).</li> </ol>

9. **Remuneration from an entity to a physician in the form of nonmonetary compensation** that exceeds the limit set for in 42 CFR 411.357(k)(1).
10. **Remuneration from an entity to a physician resulting from a loan to the physician:** (1) with an interest rate below fair market value; or (2) on terms that are unavailable from a lender that is not a recipient of the physician's referrals or business generated by the physician.
11. **Remuneration from a physician to an entity resulting from a loan to the entity:** (1) with an interest rate below fair market value; or (2) on terms that are unavailable from a lender that is not in a position to generate business for the physician.
12. **The referral by a physician owner of a hospital that temporarily expands its facility capacity above the number of operating rooms, procedure rooms, and beds** for which the hospital was licensed on March 23, 2010 (or the effective date of a provider agreement if a hospital had one in effect on December 31, 2010) without prior application and approval of facility capacity as required.
13. **Referrals by a physician owner of a hospital that converted from a physician-owned ambulatory surgical center to a hospital on or after March 1, 2020**, provided that: (i) the hospital does not satisfy one or more of the requirements of section 1877(i)(1)(A) through (E); (ii) the hospital enrolled in Medicare as a hospital during the period of the public health emergency; (iii) the hospital meets the Medicare conditions of participation and other requirements not waived by CMS during the period of public health emergency; and (iv) the hospital's Medicare enrollment is not inconsistent of the Emergency Preparedness or Pandemic Plan of the State in which it is located.
14. **The referral by a physician of a Medicare beneficiary for the provision of designated health services to a home health agency:** (1) that does not qualify as a rural provider; and (2) in which the physician has an ownership or investment interest.
15. **The referral by a physician in a group practice for medically necessary designated health services furnished by the group practice in a location that does not quality as a "same building" or "centralized building".**
16. **The referral by a physician in a group practice for medically necessary designated health services furnished by the group practice to a patient in his or her private home, an assisted living facility, or independent living facility where the referring physician's principal medical practice does not consist of treating patients in their private homes.**
17. **The referral by a physician to an entity with which the physician's immediate family member has a financial relationship if the patient who is referred resides in a rural area.**
18. **Referrals by a physician to an entity with whom the physician has a compensation arrangement that does not satisfy the writing or signature requirement(s) of an applicable exception but satisfies each other requirement of the applicable exception, unless such**

	<p>requirement is waived under one or more of the blanket waivers set forth above.</p>
<p><b>Relevant Examples</b></p>	<ul style="list-style-type: none"> <li>• An entity provides free telehealth equipment to a physician practice to facilitate telehealth visits for patients who are observing social distancing or in isolation or quarantine.</li> <li>• An entity sells personal protective equipment to a physician or permits the physician to use space in a tent or other makeshift location, at below fair market value (or provides the items or permits the use of the premises at no charge).</li> <li>• An entity provides nonmonetary compensation to a physician or an immediate family member in excess of the \$423 per year limit such as continuing medical education related to the COVID-19 outbreak in the US, supplies, food, or other grocery items, isolation-related needs (for example, hotel rooms and meals), child care, or transportation.</li> <li>• A physician refers a Medicare beneficiary who resides in a rural area for physical therapy furnished by the medical practice that is owned by the physician’s spouse and located within one mile of the beneficiary’s residence.</li> </ul>

## IV. FDA COVID-19 Emergency Use Authorizations (EUAs)

### a. In Vitro Diagnostic Products

<b>Passed Date</b>	2/4/2020
<b>Policy</b>	Authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus.
<b>Goal</b>	To accelerate the availability of tests developed by laboratories and commercial manufacturers in order to achieve more rapid and widespread testing capacity in the United States.
<b>Overview</b>	<p>The FDA guidance is aimed at laboratories and commercial manufacturers to help accelerate the use of tests developed to achieve more rapid and widespread testing capacity. The FDA provides recommendations around minimum testing, which must be performed prior to use, as well as templates for EUA requests.</p> <ul style="list-style-type: none"> <li>• Labs that meet Clinical Laboratory Improvement Amendments (CLIA) certifications and requirements can perform high-complexity testing using <b>validated</b> tests prior to EUA submission</li> <li>• States may authorize labs that meet CLIA certifications and requirements to perform high-complexity testing</li> <li>• Commercial manufacturers can develop and distribute <b>validated</b> tests prior to EUA submission</li> <li>• Commercial manufacturers and labs may develop, distribute, and use serology tests that identify antibodies to COVID-19 from clinical specimens without an EUA; this policy is limited to testing in labs or by healthcare workers at the point-of-care and does not apply to at-home testing</li> </ul>
<b>Business Benefits</b>	<ul style="list-style-type: none"> <li>• Support to accelerate the development of new tests by relaxing standard qualification timelines for laboratories and commercial manufacturers</li> </ul>
<b>Individual Level Benefits</b>	<ul style="list-style-type: none"> <li>• Rapid detection of COVID-19 cases requires availability of diagnostic testing to control the emergence of the rapidly spreading, severe illness</li> </ul>
<b>Digital Health Startup Implications</b>	<ul style="list-style-type: none"> <li>• Updated guidelines specifically bar the use of at-home sample collections in order to balance speed with safety although point-of-care tests are allowed at locations like hospitals and emergency medical care clinics; as such, many startups have halted mail-order testing-kit services as of 3/23/2020</li> </ul>
<b>Action Items</b>	<ul style="list-style-type: none"> <li>• Determine if test kits can be utilized by providers at clinical sites of care</li> </ul>
<b>Sources</b>	<ul style="list-style-type: none"> <li>• <a href="#">FDA Emergency Use Authorizations</a></li> <li>• <a href="#">Policy for Diagnostic Tests for COVID-19 during Public Health Emergency</a></li> <li>• <a href="#">Updated FDA COVID-19 testing guidelines specifically disallow at-home sample collection</a></li> </ul>

## b. Personal Protective Equipment

<b>Passed Date</b>	3/2/2020
<b>Policy</b>	Authorization of the emergency use of personal respiratory protective devices during the COVID-19 outbreak.
<b>Goal</b>	To facilitate access to critical personal protective equipment and respirators.
<b>Overview</b>	<p>Manufacturers and strategic stockpilers can submit requests to the FDA to have their products added to the EUA.</p> <ul style="list-style-type: none"> <li>• Products authorized for emergency use include masks and respirators; personal protective equipment for general purpose or industrial use (products not intended for use to prevent disease or illness) is not regulated by the FDA</li> <li>• Updated guidance includes instructions to manufacturers for importing personal protective equipment and other devices; the agency seeks to provide maximum flexibility to importers and is available to engage in order to minimize disruptions during the importing process</li> </ul>
<b>Business Benefits</b>	<ul style="list-style-type: none"> <li>• Support for importation, production, and use of personal protective equipment</li> </ul>
<b>Individual Level Benefits</b>	<ul style="list-style-type: none"> <li>• Availability of equipment needed to treat patients of COVID-19 and to control the spread of the disease</li> </ul>
<b>Digital Health Startup Implications</b>	<ul style="list-style-type: none"> <li>• Relationships with manufacturers could potentially be affected for companies that produce hardware</li> </ul>
<b>Action Items</b>	<ul style="list-style-type: none"> <li>• Immediately discuss any potential changes or delays to operations with manufacturing partners</li> <li>• Stay in close contact with manufacturing partners for any updates</li> </ul>
<b>Sources</b>	<ul style="list-style-type: none"> <li>• <a href="#">FDA Emergency Use Authorizations</a></li> <li>• <a href="#">COVID-19 Update: FDA takes action to increase U.S. supplies through instructions for PPE and device manufacturers</a></li> <li>• <a href="#">U.S. Customs &amp; Border Protection Cargo Systems Messaging Service</a></li> </ul>

### c. Other Medical Devices

<b>Pass Date</b>	3/24/2020
<b>Policy</b>	Authorization of emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 outbreak.
<b>Goal</b>	To mitigate shortages of medical devices by reducing barriers in the production of ventilators.
<b>Overview</b>	<p>Manufacturers and other stakeholders can submit requests to the FDA to have their products added to the EUA.</p> <p>Additional guidelines include:</p> <ul style="list-style-type: none"> <li>• Flexibility in enforcement of premarket review requirements for modifications to ventilator devices (e.g. adding wireless or Bluetooth capability for remote monitoring) or added production lines and alternative sites</li> <li>• Hospitals and healthcare professionals may use ventilators intended for other environments (e.g. repurposing ventilators normally used for transporting patients in an ambulance) or beyond their indicated shelf life; the FDA provides recommendations for other alternatives to be considered, including CPAP devices used for treating sleep apnea</li> </ul>
<b>Business Benefits</b>	<ul style="list-style-type: none"> <li>• Medical devices makers can more easily make changes to existing products, such as changes to suppliers or materials, to address current manufacturing limitations or supply shortages</li> <li>• Other manufacturers, such as auto makers, can more easily repurpose machines they have now to serve as ventilators</li> </ul>
<b>Individual Level Benefits</b>	<ul style="list-style-type: none"> <li>• Increased availability of ventilators and accessories, as well as other respiratory devices, to support patients with respiratory failure or difficulty breathing</li> </ul>
<b>Digital Health Startup Implications</b>	<ul style="list-style-type: none"> <li>• Relationships with manufacturers could potentially be affected for companies that product hardware</li> </ul>
<b>Action Items</b>	<ul style="list-style-type: none"> <li>• Immediately discuss any potential changes or delays to operations with manufacturing partners</li> <li>• Stay in close contact with manufacturing partners for any updates</li> </ul>
<b>Sources</b>	<ul style="list-style-type: none"> <li>• <a href="#">FDA Emergency Use Authorizations</a></li> <li>• <a href="#">FDA Continues to Facilitate Access to Crucial Medical Products, including Ventilators</a></li> <li>• <a href="#">Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices during the COVID-19 Public Health Emergency</a></li> </ul>

#### d. Therapeutics

<b>Passed Date</b>	3/28/2020
<b>Policy</b>	Authorization of hydroxychloroquine sulfate and chloroquine phosphate products donated to the Strategic National Stockpile (SNS) to be distributed and used for certain hospitalized patients with COVID-19.
<b>Goal</b>	Distribution of drugs from the SNS to states for doctors to prescribe to adolescent and adult patients hospitalized with COVID-19, as appropriate, when a clinical trial is not available or feasible.
<b>Overview</b>	<ul style="list-style-type: none"> <li>• The EUA requires that fact sheets that provide important information about using chloroquine phosphate and hydroxychloroquine sulfate in treating COVID-19 be made available to health care providers and patients, including the known risks and drug interactions</li> <li>• The SNS will work with FEMA to ship donated doses to states</li> <li>• Hydroxychloroquine sulfate and chloroquine phosphate are oral prescription drugs approved to treat malaria and other disease</li> <li>• There are no currently approved treatments for COVID-19, but these drugs have shown activity in lab studies against coronaviruses; clinical trials are still needed to provide scientific evidence of effectiveness</li> </ul>
<b>Business Benefits</b>	<ul style="list-style-type: none"> <li>• Companies have ramped up production to provide additional supplies of the medication to the commercial market.</li> </ul>
<b>Individual Level Benefits</b>	<ul style="list-style-type: none"> <li>• Potential benefits in the treatment of hospitalized COVID-19 patients</li> </ul>
<b>Digital Health Startup Implications</b>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
<b>Sources</b>	<ul style="list-style-type: none"> <li>• <a href="#">FDA Emergency Use Authorizations</a></li> <li>• <a href="#">HHS accepts donations of medicine</a></li> </ul>

## V. Insurance Resources

### a. Business Interruption Resources

<b>Benefit</b>	Optional coverage that covers a company's loss of income after a disaster. This coverage may be purchased as part of a comprehensive multi-peril commercial policy.
<b>Impacted Organizations</b>	Companies with current business interruption insurance policies.
<b>Other Considerations</b>	Many state insurance company policies have exclusion criteria that do not cover interruptions caused by a disease outbreak or virus.
<b>Action Items</b>	Companies are encouraged to file claims as some insurance carriers are considering providing limited coverage.

### b. Workers' Compensation

<b>Benefit</b>	Workers' compensation claims from health care providers and first responders involving COVID-19 may be allowed. Other claims that meet certain criteria for exposure will be considered on a case-by-case basis.
<b>Impacted Organizations</b>	All employers with workers' compensation policies with employees who meet criteria for COVID-19 related workers' compensation claims.
<b>Other Considerations</b>	Not applicable for most start-ups unless the workforce involves care delivery. If contraction of COVID-19 is incidental to the workplace or common to all employment, a claim for exposure to and contraction of the disease will be denied.
<b>Action Items</b>	Companies are encouraged to file workers' compensation claims as applicable.

### c. Unemployment Insurance Changes

<b>Benefit</b>	Maximum unemployment insurance benefits have been extended by one month (now 4 months) and an additional \$600 per week has been added for all unemployment filers.
<b>Impacted Organizations</b>	All employers nationwide.
<b>Other Considerations</b>	Eligibility requirements have been broadly expanded so that most employees who have a substantial reduction in pay are now eligible including: layoffs, furloughed employees, those with hours substantially cut, leave related to care of family members, gig economy workers, and self-employed individuals.
<b>Action Items</b>	Consult your attorney to determine whether your employees should claim unemployment vs. the FMLA benefits companies are required to offer.



## VI. Commercial Payer Policy Changes

Most common policy updates payers are providing to their members in response to COVID-19.

	Waiving cost-sharing or prior auths for COVID-19 screening or diagnostic testing*	Waiving cost-sharing or prior auths for in-patient treatment of COVID-19 or complications*	Encouraging use of telehealth services	Expanding coverage of and access to telehealth services	Waiving cost-sharing of telehealth services	Providing behavioral health appointments or programs for stress and anxiety	Relaxing Prescription Refill Limits
<b>Payer</b>	<i>Note: specific details of policy coverage (e.g. time, service, location) vary by payer; many self-insured plans are making their own decisions</i> <i>*waivers of cost-sharing may vary depending on whether the provider is in or out of network for the specific health plan; the level of cost-sharing may also differ (e.g. co-pay, deductible, coinsurance)</i>						
Aetna	X	X	X	X	X	X	
AllWays Health Partners	X	X	X		X		
AmeriHealth New Jersey	X		X		X		
Anthem	X		X	X	X		X
AvMed	X		X				X
<b>Arkansas BCBS and Health Advantage</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>			<b>X</b>
BCBS Association	X		X		X		X
BCBS of Arizona	X	X	X	X	X		X
Blue Shield of California	X	X	X		X		
Blue Cross of Idaho	X		X	X	X		
BCBS of Illinois			X	X	X		
BCBS of Kansas City	X	X	X		X	X	X
BCBS of Massachusetts	X	X	X		X		X
BCBS of Michigan	X		X	X			X
BCBS of Minnesota	X	X	X	X			X
BCBS of Montana	X		X	X	X		
BCBS of Nebraska	X		X		X		X
BCBS of New Mexico	X						
BCBS of North Carolina	X		X	X			X
BCBS of Oklahoma	X		X		X		
BCBS of Tennessee			X	X			
BCBS of Texas	X				X		
Capital BlueCross	X	X	X		X		X
CareFirst BCBS	X	X					X
Florida Blue	X		X	X	X	X	X
<b>Horizon BCBS of New Jersey</b>	<b>X</b>		<b>X</b>		<b>X</b>		<b>X</b>

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Payer	<i>Note: specific details of policy coverage (e.g. time, service, location) vary by payer; many self-insured plans are making their own decisions</i> <i>*waivers of cost-sharing may vary depending on whether the provider is in or out of network for the specific health plan; the level of cost-sharing may also differ (e.g. co-pay, deductible, coinsurance)</i>						
Independence Blue Cross	X		X				X
Premera Blue Cross			X	X			
Regence Blue Shield of Idaho	X		X	X			X
Regence BCBS of Oregon	X						X
Regence BCBS of Utah	X		X	X			X
Regence BlueShield of Washington	X		X	X			X
BCBS Federal Employee Program	X		X		X		X
Wellmark BCBS			X	X	X		X
Bright Health	X		X		X		X
Centene	X	X					
<b>Cigna</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>		<b>X</b>	<b>X</b>
ConnectiCare			X		X		
First Choice Health			X	X	X		
Geisinger Health Plan	X		X	X	X		X
Harvard Pilgrim Health Care	X	X	X		X		X
Health Alliance Plan (HAP)	X						
Health Care Service Corporation (HCSC)	X						
Healthfirst, Inc.	X						
Health Net	X						
HealthPartners	X						
Highmark	X		X	X	X		
Humana	X	X	X	X	X		X
Inter Valley Health Plan	X						X
Kaiser Permanente	X						
L.A. Care	X	X					
Magellan Health			X	X		X	

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Medica Health Plan	X		X				
Medical Mutual of Ohio	X						
Moda Health	X						
Molina Healthcare**	X						
MVP Health Care	X		X		X		
Optima Health	X		X		X		
Oscar	X		X		X		
PacificSource	X						X
Piedmont Community Health Plan	X		X		X	X	X
<b>Priority Health</b>			<b>X</b>		<b>X</b>		
QualChoice Health Insurance	X		X		X		
Quartz Health Solutions	X		X		X		
Sanford Health Plan	X						X
SCAN Health Plan			X	X			
TakeCare	X						X
United Healthcare	X	X	X	X	X		
UPMC and UPMC Health Plan	X		X		X		X
Valley Health Plan	X	X	X				X
Viva Health	X		X		X		

\*\*launched Coronavirus Chatbot as an enhanced digital tool for members seeking information about COVID-19 risk factors and personal risk profiles