

**AdvaMed Summary of Key Medtech or Related Provisions of
S. 3548 The Coronavirus Aid, Relief, and Economic Security Act (CARES)**

Key Issue Area	Section	Provision Description
Supply Chain and Device Shortages	Sec. 3101	Directs the National Academies to study the manufacturing supply chain of drugs and medical devices and provide Congress with recommendations to strengthen the U.S. manufacturing supply chain.
	Sec. 3102	Requiring the strategic national stockpile to include certain types of medical supplies: Clarifies that the Strategic National Stockpile can stockpile medical supplies, such as the swabs necessary for diagnostic testing for COVID-19.
	Sec. 3103	Treatment of respiratory protective devices as covered countermeasures: Provides permanent liability protection for manufacturers of personal respiratory protective equipment, such as masks and respirators, in the event of a public health emergency, to incentivize production and distribution.
	Sec. 3121	Requires reporting of a discontinuance or interruption in manufacture of certain devices during a Public Health Emergency. Devices that are life-supporting, life-sustaining, or intended for use in emergency medical care, or during surgery, or which the Secretary determines information is needed during or in advance of a public health emergency must notify the Secretary during, or in advance of, a declared public health emergency of a permanent discontinuance or interruption in manufacturing that is likely to lead to a meaningful disruption in the supply of that device in the United States, and reasons for the interruption or discontinuance. Establishes a device shortage list.
Diagnostic Testing	Sec. 3201	Clarifies definition of in vitro diagnostic test for COVID-19 (amending section 6001(a) of Families First Coronavirus Response Act)
	Sec. 3202	Requires group health plans or health insurers to pay providers of diagnostic tests at either (1) a negotiated rate or (2) the provider's "cash price", which must be published on a public internet website. Provision includes potential for Civil Monetary Penalties for providers not in compliance.
	Sec. 3203	Requires group health plans or health insurers to cover, without cost-sharing, qualifying coronavirus prevention services, including (1) preventive services with Grade A or B recommendation from USPSTF or (2) immunization with a recommendation from the Advisory Committee on Immunization Practices of the CDC.

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	Sec. 3717	Clarifies definition of in vitro diagnostic tests for COVID-19 covered without cost-sharing under Medicaid and CHIP (amending section 6004 of Families First Coronavirus Response Act)
Data Privacy and HIPAA	Sec. 3221	Amends the Public Health Service Act with regard to confidentiality and disclosure of substance abuse disorder records, incorporating HIPAA definitions and references and including provisions related to breach and requires updating of regulations pertaining to notice of privacy practices.
	Sec. 3224	Requires Secretary to issue guidance on sharing of PHI under HIPAA during the COVID-19 emergency.
Telehealth Provisions	Sec. 3212	Reauthorizes HRSA grant programs that promote the use of telehealth technologies for health care delivery, education, and health information services. Expands grant funding for evidence-based telehealth networks and telehealth technologies.
	Sec. 3701	Authorizes a “safe harbor” for high deductible health plans for failing to have a deductible for telehealth and other remote care services.
	Sec. 3703	Authorizes waivers for telehealth services to be provided by practitioners, other than physicians and other providers authorized under Medicare's telehealth benefit.
	Sec. 3704	Authorizes Medicare payment for telehealth services provided by Federally qualified health centers or rural health clinics, waiving a requirement that payment be made only to certain practitioners who provide a telehealth visit in lieu of a face-to-face visit.
	Sec. 3705	Waives requirement for face-to-face visits between home dialyses patients and physicians during emergency period.
	Sec. 3706	Allows use of telehealth to conduct face-to-face encounter prior to the recertification of eligibility for hospice care during the emergency period.
	Sec. 3707	Encourages use of “telecommunications systems,” including for remote patient monitoring, for furnishing of home health services during the emergency period.
DMEPOS	Sec. 3712	For DMEPOS items subject to competitive bidding and provided in rural and non-contiguous non-CBA areas, extends the 50/50 transition payment amount (50 percent based on the adjusted payment amount determined by competitive bidding in the area

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		<p>and 50 percent on the fee schedule amount for the item) beyond Dec. 31, 2020, and to the end of the emergency period established in recently passed legislation.</p> <p>For DMEPOS items subject to competitive bidding and provided in other non-CBA areas, this section also provides a 75/25 transition payment (75 percent determined by competitive bidding for the area and 25 percent on the fee schedule amount for the item) for the period beginning March 6, 2020, through to the end of the emergency period. This transition payment would replace for this period the requirement that payments in such areas be equal to 100 percent of the adjusted payment based on competitive bidding for the area.</p>
Adjustment of Sequestration	Sec. 3709	Temporary suspension of Medicare Sequestration. This section would temporarily lift the Medicare sequester, which reduces payments to providers by 2 percent, from May 1 through December 31, 2020
Inpatient DRG Payment and IRF/LTCH requirements	Sec. 3710	Requires Secretary to increase the DRG weighting factor by 20 percent for an individual diagnosed with COVID-19 during national emergency. Budget neutrality will not apply for such increase.
	Sec. 3711	Secretary shall waive the requirement that patients of an inpatient rehabilitation facility receive at least 3 hours of therapy a day. In addition, this section would allow a Long Term Care Hospital (LTCH) to maintain its designation even if more than 50 percent of its cases are less intensive. It would also temporarily pause the current LTCH site-neutral payment methodology.
Home & Community Based Waivers	Sec. 3715	Allows state Medicaid programs to pay for training and consulting with providers to in rural and underserved areas on treating COVID-19.
Clarification Regarding Uninsured Individuals	Sec. 3716	This section would clarify a section of the Families First Coronavirus Response Act of 2020 (Public Law 116-127) by ensuring that uninsured individuals can receive a COVID-19 test and related service with no cost-sharing in any state Medicaid program that elects to offer such enrollment option.

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Clinical Laboratory Payment Reporting and Payments	Sec. 3718	Delays private payer data reporting for one year (January – March 2022) and freezes payment rates for 2021 and shifts the scheduled 15 percent cap in payment reductions to 2022-2024
Providing Hospitals Medicare Advanced Lump Sum or Periodic Payments	Sec. 3719	This section would expand, for the duration of the COVID-19 emergency period, an existing Medicare accelerated payment program. Hospitals, especially those facilities in rural and frontier areas, need reliable and stable cash flow to help them maintain an adequate workforce, buy essential supplies, create additional infrastructure, and keep their doors open to care for patients. Specifically, qualified facilities would be able to request up to a six month advanced lump sum or periodic payment. This advanced payment would be based on net reimbursement represented by unbilled discharges or unpaid bills. Most hospital types could elect to receive up to 100 percent of the prior period payments, with Critical Access Hospitals able to receive up to 125 percent. Finally, a qualifying hospital would not be required to start paying down the loan for four months, and would also have at least 12 months to complete repayment without a requirement to pay interest.
Medicaid	Sec. 3813	Eliminates the \$4 billion Medicaid DSH cuts in FY 2020 and reduces the cut for FY 2021 from \$8 billion to \$4 billion. No additional cuts after the current end date of FY 2025.
Federal Food Drug and Cosmetic Act	Sec. 3856 (a)	Certificates to foreign governments (CFG) technical fix.
Tax	Sec. 2301	Provides refundable payroll tax credit for 50% of wages paid to employees during the COVID-19 crisis. Only available to employers whose operations were suspended and profits decreased compared to same quarter in the prior year.
	Sec. 2306	Temporary increase of the limitation of interest businesses can deduct on tax returns. Increases limitation threshold increased from 30% to 50% of EBITDA for tax years beginning in 2019 and 2020.
	Sec. 2302	Delay of all employer-side OASDI payroll taxes (6.2%, not the Medicare/Hi 1.45%), payable over two years with half due by 12/31/21 and the remainder due by 12/31/22.
	Sec. 2303 & 2304	Net Operating Loss tax relief – Carryback: NOLs from tax years 2018, 2019, or 2020 may be carried back five years; Limitation: 80% Income limitation suspended for losses arising in taxable years beginning before 12/31/20.

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	Sec. 2305	Corporate AMT Credits treated as refundable for taxable years beginning in 2018 and beyond.
	Sec. 2307	Qualified improvement property (technical correction to TCJA): confirms repairs and improvements are eligible for a 15-year class life and eligible for bonus depreciation/full expensing.
	Sec. 2308	Exemption from alcohol excise taxes for hand sanitizer production through 12/31/20.
	Sec. 4007	Aviation excise taxes: taxes for airline tickets, segments, and cargo, and aviation fuel, from date of enactment through 12/31/20.
Small Business	Sec. 1102, 1104, 1110 & 1114	<p>Provides \$350 billion in small business employee retention loans for businesses, nonprofits, veteran’s organizations, and Tribal businesses with up to 500 employees as part of the Paycheck Protection Program. Sole proprietors, independent contractors, and self-employed are also eligible for loans. Covered loan period is Feb 15 – June 30, 2020.</p> <p>Loan provided is based off payroll in past years and the loan can be used for payroll support, such as employee salaries, paid sick or medical leave, insurance premiums, and mortgage interest, rent, and utility payments. Maximum loan is \$10 million.</p> <p>Some loans may be forgiven, but the amount forgiven is equal to the amount spent on payroll costs after the loan originates, and prior spending on mortgage, leases, and utility payments. Payroll costs that count toward loan forgiveness do not include compensation above \$100,000 in wages. The amount forgiven will be reduced proportionally by the number of employees retained compared to the prior year (no penalty for re-hiring previously laid off workers).</p> <p>Expands eligibility for SBA’s Economic Injury Disaster Loans (EIDL), and allows businesses that apply for an EIDL expedited access to capital through an Emergency Grant—an advance of \$10,000 within three days to maintain payroll, provide paid sick leave, and to service other debt obligations. \$10 billion would be provided to support the expanded EIDL program.</p>

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		Waives prepayment fees, borrower and lender fees, and ability to repay requirements. Regulations will be put out in about 15 days.
	Disaster Loans Program Account (p. 675)	Provides \$562M to remain available until expended, to prevent, prepare for, and respond to coronavirus, domestically or internationally, for the cost of direct loans authorized by section 7(b) of the Small Business Act and for administrative expenses to carry out the disaster loan program authorized by section 7(b) of the Small Business Act.
Economic Stabilization Loans	Sec. 4003-4004 & 4018-4020	<p>Federal Reserve lending program to provide liquidity for industry in the form of loans, loan guarantees and other investments.</p> <p>Treasury-Administered direct loans specifically, \$25 billion to passenger air carriers, \$4 billion to cargo air carriers, \$17 billion to “businesses critical to maintaining national security,”. \$454 billion dedicated for loans/loan guarantees/other methods of investing directed by Treasury/Federal Reserve. Procedures and regulations due no more than 10 days after enactment.</p> <p>Specific restrictions on exec salaries, establishment of IG within Treasury for Pandemic Recovery. Restricts companies with ties to President/VP/Department head/Congress are not eligible. Creates Congressional Oversight Committee.</p>
Title VIII Funding For HHS	CDC-Wide Activities and Program Support (p. 728)	Additional amount of \$4.3B for “CDC–Wide Activities and Program Support” to remain available until September 30, 2024, to prevent, prepare for, and respond to coronavirus, domestically or internationally.
	NIH (p. 730)	Additional amount \$103.4M for “National Heart, Lung, and Blood Institute” to remain available until September 30, 2024, to prevent, prepare for, and respond to coronavirus, domestically or internationally.
	National Institute of Allergy and	Additional amount of \$706M to remain available until September 30, 2024, to prevent, prepare for, and respond to coronavirus, domestically or internationally. Not less than \$156M of the amounts provided under this heading in this Act shall be provided for the study of, construction of, demolition of, renovation of, and acquisition of equipment or,

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	Infectious Diseases (p. 731)	vaccine and infectious diseases research facilities of or used by NIH, including the acquisition of real property.
	SAMHSA Health Surveillance and Program Support (pgs. 733-734)	\$425M to remain available through September 30, 2021, to prevent, prepare for, and respond to coronavirus, domestically or internationally; of the amount appropriated under this heading in this Act, not less than \$250M is available for the Certified Community Behavioral Health Clinic Expansion Grant program; of the amount appropriated under this heading in this Act, not less than \$100M is available for activities authorized under section 501(o) of the Public Health Service Act.
	Public Health and Social Services Emergency Fund - BARDA (pgs. 743-752)	<p>Biomedical Advanced Research and Development Authority (BARDA): An amount of \$27.14 billion to remain available until September 30, 2024, to prevent, prepare for, and respond to coronavirus, domestically or internationally, including the development of necessary countermeasures and vaccines, prioritizing platform-based technologies with U.S.-based manufacturing capabilities, the purchase of vaccines, therapeutics, diagnostics, necessary medical supplies, as well as medical surge capacity, addressing blood supply chain, workforce modernization, telehealth access and infrastructure, initial advanced manufacturing, novel dispensing, enhancements to the U.S. Commissioned Corps, and other preparedness and response activities.</p> <p>Manufacturing Innovation: Such funds may be used to develop and demonstrate innovations and enhancements to manufacturing platforms to support such capabilities.</p> <p>Strategic National Stockpile: Of the amount appropriated under this paragraph in this Act, not more than \$16B shall be for the Strategic National Stockpile under section 319F–2(a) of such Act.</p> <p>GRANTS to providers to cover expenses and lost revenues: (p. 750-752) Provides \$100 billion for “Public Health and Social Services Emergency Fund” to remain available until expended, to prevent, prepare for, and respond to coronavirus, domestically or internationally, for necessary expenses to reimburse, through grants or other</p>

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		<p>mechanisms, eligible health care providers for health care related expenses or lost revenues that are attributable to coronavirus. These funds may not be used to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse. “Eligible health care providers” means public entities, Medicare or Medicaid enrolled suppliers and providers, and such for-profit entities and not-for-profit entities not otherwise described in this proviso as the Secretary may specify, within the United States (including territories), that provide diagnoses, testing, or care for individuals with possible or actual cases of COVID–19. The Secretary of Health and Human Services shall, on a rolling basis, review applications and make payments under this paragraph in this Act. Funds appropriated under this paragraph in this Act shall be available for building or construction of temporary structures, leasing of properties, medical supplies and equipment including personal protective equipment and testing supplies, increased workforce and trainings, emergency operation centers, retrofitting facilities, and surge capacity. The term “payment” means a pre-payment, prospective payment, or retrospective payment, as determined appropriate by the Secretary. To be eligible for a payment under this paragraph, an eligible health care provider shall submit to the Secretary of Health and Human Services an application that includes a statement justifying the need of the provider for the payment and the eligible health care provider shall have a valid tax identification number.</p>