

# CORONAVIRUS INFORMATION & UPDATES

August 17, 2020

## Senate Republicans Introduce the Health, Economic Assistance, Liability Protection and Schools Act (HEALS Act)

**\*\*\*This legal development is still in progress. We will update this Alert as the Act makes its way through the legislative process.\*\*\***

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At the end of July, Senate Republican leaders announced the Health, Economic Assistance, Liability Protection and Schools Act (HEALS). The HEALS Act is a package of eight separate bills worth nearly \$1 trillion and proposed by Senate Republicans for negotiation with the House on its HEROES Act (HEROES), a nearly \$3 trillion bill passed by the House on May 15, 2020 in response to the COVID-19 outbreak. Ropes & Gray's Alert on the HEROES Act can be found [here](#).

This Alert highlights notable proposals of particular interest to the health care and life sciences industries. These include (i) extensions of key CARES Act funding provisions such as the Public Health and Social Services Emergency Fund Provider Relief Fund (the "Provider Relief Fund"); (ii) extensions of certain telehealth services and of the authority of the Secretary of Health and Human Services (HHS) to waive or modify certain telehealth requirements; (iii) limitations on liability for business entities and health care providers; and (iv) support and funding to address COVID-19 in skilled nursing facilities and nursing facilities. The HEALS Act appropriates significantly less funding to state and local governments and the Provider Relief Fund than the HEROES Act, and notably absent are key priorities identified in the House's HEROES Act, such as hazard pay funding for essential workers and funding for renters and homeowners. Ropes & Gray's Alert on the tax provisions of the HEALS Act can be found [here](#).

It appears unlikely that the legislation will be passed in its current form due to the absence of support from House Democrats, and it is unclear what, if any, of these proposals ultimately will be enacted. However, the proposals in the HEALS Act, together with the HEROES provisions passed by the House, represent a baseline from which the final legislation is likeliest to result.

Most of the HEALS Act proposals of greatest interest to health care and life sciences stakeholders derive from six of the eight bills:

- [Coronavirus Response Additional Supplemental Appropriations Act](#)
- [American Workers, Families, and Employers Assistance Act](#)
- [Continuing Small Business Recovery and Paycheck Protection Program Act](#)
- [Safe to Work Act](#)
- [Restoring Critical Supply Chains and Intellectual Property Act](#)
- [Safely Back to School and Back to Work Act](#)

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## Replenishing of Key CARES Act Financial Support Programs

The HEALS Act proposes supplemental appropriations for a number of funding programs that specifically impact the health care industry. Their replenishment would provide needed access to capital, especially to hospitals and other providers that often rely on slim margins, particularly in light of suspension of elective procedures in many states.

***Provider Relief Fund: Additional Funding*** – In contrast to the \$100 billion appropriated in the HEROES Act, the HEALS Act’s supplemental appropriations bill provides only an additional \$25 billion to the Provider Relief Fund established by the CARES Act, which passed in March 2020. Congress established the fund to reimburse eligible health care providers for health care-related expenses or lost revenues attributable to COVID-19. To receive funding, recipients are required to attest that they meet various terms and conditions. Apart from new funding, the current bill leaves intact the terms and conditions established under the CARES Act and subsequent regulations.

***Accelerated and Advance Payment Programs Repayment Terms Extended*** – The HEALS Act extends relief to Medicare providers and suppliers that received advance payments under the Accelerated and Advance Payment Programs. The CARES Act permitted Medicare Part A- and Part B-enrolled providers and suppliers to request and receive up to three months (six months for hospitals) of Medicare advanced payments. From March 28 to April 26, CMS approved over 21,000 applications under the program, including \$59.6 billion in payments to Part A providers (hospitals) and almost 24,000 applications totaling \$40.4 billion in payments to Part B suppliers (*e.g.*, doctors, non-physician practitioners and DME suppliers). The CARES Act provides that the payments are subject to repayment via offset from Medicare payments beginning 120 days after issuance of the advanced payments, to be fully repaid within 210 days (one year for hospitals). The HEALS Act extends the repayment timeline of the payments to the following:

- Hospitals begin recoupment after 270 days, with at least 18 months to repay the outstanding balance in full;
- Part B participants begin recoupment after 270 days, with at least 14 months to make the repayment.

The HEROES Act also made provider-friendly changes to the Accelerated and Advance Payment Programs, which include pushing back the recoupment start date to one year from the payment date, extending the repayment period to two years, lowering interest rates on balances remaining past the repayment period to 1%, and reducing the per-claim recoupment rate to a maximum of 25%.

***Other Additional Funding for Providers*** – The HEALS Act also provides supplemental funding to the following programs:

- \$4.5 billion to the Substance Abuse and Mental Health Services Administration, with allocations to various mental and behavioral health, substance use treatment, and suicide prevention programs for treatment needs arising as a result of the COVID-19 outbreak. This funding supplements the CARES Act’s \$425 million appropriation and is larger than the \$3 billion allocated in the HEROES Act.
- \$225 million in grants to rural health clinics. The funds are to be distributed using the procedures developed for the Provider Relief Fund. This funding supplements the \$225 million appropriated to rural health clinics under the Paycheck Protection Program and Health Care Enhancement Act.

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- \$7.6 billion in funding for the Health Resources and Services Administration – Primary Care for grants, cooperative agreements, and other necessary expenses for community-based primary care organizations serving vulnerable populations. The CARES Act previously increased funding for community health centers from \$2.5 billion to \$4 billion.

***Paycheck Protection Program: Allowable Expenditures Expanded and Second Loans Authorized*** – The HEALS Act provides an additional \$190 billion in funding for the Paycheck Protection Program (PPP). The PPP provides small businesses with loans that are forgiven if used towards payroll, interest on mortgages, rent, and utilities. However, the bill would expand spending categories to include certain operations expenditures, property damage, supplier costs, and worker protection. Companies would be able to use PPP loans on those categories without losing their eligibility for loan forgiveness. Additionally, borrowers would have flexibility on when to spend funds.

The bill also allows businesses with fewer than 300 employees and revenues declining by 50% or more in the first or second quarters of this year to take out a second PPP loan. The maximum loan size for a second draw is the lesser of the 2.5 times the average total monthly payment for payroll costs incurred or paid by the eligible entity during the one-year period before the date the loan was made, which mirrors the original PPP loan parameter, or \$2 million. The maximum loan amount within a 90-day period cannot exceed \$10 million (including the total combined value of a first and second PPP loan). Businesses taking their first draw may now only borrow a maximum of \$2 million, where previously the cap was set to \$10 million. The HEROES Act also eases PPP restrictions on loans but does not appropriate any additional funds to the program.

***Employee Retention Tax Credit Increased*** – The HEALS Act proposes to increase the tax credit from 50 percent under the CARES Act to 65 percent of qualified employee wages paid between March 13, 2020 and December 31, 2021. It also increases the qualifying wage limit from \$10,000 for all calendar quarters to \$10,000 in any quarter and \$30,000 in the aggregate for all calendar quarters. In addition, the bill lowers the amount required to qualify for the tax credit from a 50 percent decline to a 25 percent decline in gross receipts. The HEROES Act contains a more generous proposal to expand the scope of the Employee Retention Tax Credit. It expands the tax credit to 80% of qualified employee wages and increases the wage cap to \$12,000 per calendar quarter, for a maximum credit of \$36,000. It also lowers the threshold to permit employers who experience a 10% drop in gross receipts for the calendar quarter to claim part of the credit.

### Funding for COVID-19 Testing

The HEALS Act's supplemental appropriations bill allocates \$16 billion to COVID-19 testing, contract tracing, and surveillance at the state level, which would be added to the \$9 billion that remains unallocated from the Paycheck Protection Program and Health Care Enhancement Act. Laboratories, medical device manufacturers, and test developers may have increased opportunities to expand operations if testing continues to expand across the country.

### Funding for the Development of COVID-19 Vaccines and Therapeutics

The HEALS Act's supplemental appropriations bill allocates \$15.5 billion to the National Institutes of Health (NIH), with the funds dedicated to the Office of the Director with use toward supporting the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership. Through the Public Health and Social Services Emergency Fund, the Act would also appropriate \$6 billion for developing and executing a new COVID-19



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vaccination distribution campaign coordinated through the CDC and \$20 billion for the Biomedical Advanced Research and Development Authority for vaccine, therapeutic, and diagnostic development.

The HEALS Act establishes a process for public and private entities to access samples of infectious disease agents to support the development of diagnostic tests, treatments, or vaccines and to address emerging infectious diseases. It also allows the CDC to contract with public and private entities for immediate and rapid development, validation, and dissemination of diagnostic tests, for biosurveillance and for other immediate public health response activities addressing emerging infectious diseases. This presents opportunities for testing laboratories, pharmaceutical companies, and medical device manufacturers to provide products and services critical to the nation's long-term approach to infectious disease management.

## Extension of Telehealth Waivers

The HEALS Act authorizes an extension of telehealth waivers through 2021 and potentially beyond, a recognition of the impact of the COVID-19 pandemic on the rapid adoption of telehealth across the health care industry.

***Medicare Telehealth Waivers: HHS Authority Extended but Not Mandated*** – The HEALS Act provides that, if the COVID-19 public health emergency period expires prior to December 31, 2021, the Secretary may waive or modify Medicare coverage requirements for telehealth through December 31, 2021. Telehealth providers should note that while the bill provides for the extension of the Secretary's authority, the Secretary would not be required to extend any specific waivers or modifications. The bill also requires the Medicare Payment Advisory Commission to evaluate and report to Congress its evaluation of the expansion of telehealth services due to the COVID-19 outbreak, including whether expansions should be continued and how Medicare should pay for telehealth services after the COVID-19 public health emergency period expires.

***Extending Medicare Telehealth Flexibility for Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs)*** – The HEALS Act extends the expansion of Medicare coverage for telehealth by waiving for five years the originating site geographic requirement for FQHC and RHC telehealth services beyond the end of the COVID-19 public health emergency period. During the proposed additional five-year period, however, the waivers regarding pre-existing patient relationship in place during the COVID-19 pandemic would no longer apply, and payment would only be made for FQHC and RHC telehealth services furnished by an FQHC or RHC that furnished health services to an individual during the three-year period prior to providing the telehealth service.

## Tort Reform for Businesses and Health Care Providers

Among the most politically controversial proposals of the HEALS Act are substantial liability protections, opposed by Democrats, that would create significant barriers to claims against employers and health care providers resulting from personal injuries related to COVID-19. These proposals were subject to considerable public discussion and may become a focal point of discussions between House Democrats and Senate Republicans.

***Liability Limitations for Individuals and Entities Engaged in Businesses, Services, Activities, or Accommodations*** – The HEALS Act proposes broad liability protections in an effort to address the risk of litigation that may be viewed as an impediment to health care efforts and the national reopening. The bill provides for an exclusive cause of action, the

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“coronavirus exposure action,” for persons who suffered or are at risk of suffering personal injury and who allege that an actual, alleged, feared or potential for exposure to COVID-19 caused such personal injury or risk thereof, which occurred in the course of businesses, services, activities or accommodations from December 1, 2019 through October 1, 2024 or the end of the COVID-19 public health emergency period. Subject to certain exceptions, this liability reform preempts and supersedes any Federal, State, or Tribal law related to recovery for personal injuries caused by actual, alleged, feared, or potential for exposure to COVID-19.

- Plaintiffs must prove the individual or entity engaging in the businesses, services activities, or accommodations:
- was not making reasonable efforts to comply with governmental standards,
- engaged in *gross negligence or willful misconduct* causing an actual exposure to COVID-19, and
- the exposure caused the personal injury.

A written or published policy on COVID-19 transmission that complied with applicable government standards provides a rebuttable presumption that reasonable efforts have been made. However, a plaintiff may rebut this presumption by establishing non-compliance with such written or published policy. Third-party liability in a COVID-19 exposure action would be limited to those with an obligation under general common law principles to control third-party acts and third-party agents.

***Liability Limitations for Health Care Providers*** – The HEALS Act also provides for an exclusive cause of action against a health care provider, the “coronavirus-related medical liability action.” Plaintiffs could bring the action if they suffer a personal injury and allege any harm, damage, breach, or tort that resulted in such injury was caused by, arose out of, or was related to a health care provider’s act or omission in arranging for or providing coronavirus-related health care services from December 1, 2019 through October 1, 2024 or the end of the COVID-19 public health emergency period.

The “health care provider” includes, in part, any person who is authorized or licensed to provide health care or considered by law to be a health care provider, health care professional, health care institution, or health care facility. This includes health care facility administrators, supervisors and board members responsible for directing, supervising, or monitoring “coronavirus-related health care services” and certain volunteer health care professionals.

“Coronavirus-related health care services” means services provided by a “health care provider” that relate to (i) the diagnosis, prevention or treatment of coronavirus; (ii) the assessment or care of a confirmed or suspected case of coronavirus; or (iii) the care of any individual who is admitted to, presents to, receives services from, or resides at a health care provider for any purpose during the COVID-19 public health emergency period if such provider’s decisions or activities concerning the individual are impacted by COVID-19.

Subject to certain exceptions, this liability reform would preempt and supersede any Federal, State, or Tribal law related to recovery for personal injuries caused by, arising out of, or related to an act or omission by a health care provider in the course of arranging for or providing coronavirus-related health care services.

To succeed in a coronavirus-related medical liability action, a plaintiff must prove (i) *gross negligence or willful misconduct* by the health care provider and (ii) that the alleged harm, damage, breach, or tort resulting in the personal

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injury was directly caused by such. The bill provides that acts, omissions, or decisions resulting from a resource of staffing shortage are not considered gross negligence or willful misconduct.

**Limits on Damages for Coronavirus-related Actions Generally** – The HEALS Act limits compensatory damages to economic losses incurred, subject to a court award of damages for a determination of willful misconduct. Punitive damages would also be limited to a determination of willful misconduct and an amount not to exceed compensatory damages. The amount of monetary damages would also be reduced by compensation received by other sources, for example, insurance or government reimbursement.

**Relation to Labor and Employment Laws** – The HEALS Act also provides limitations on violations under certain covered Federal employment laws. It provides that, in actions, proceedings, or investigations resulting from or related to actual, alleged, feared or potential COVID-19 exposure or working condition changes caused by a law, rule, declaration, or order related to COVID-19, an employer shall not be subject to enforcement proceedings or liability under such covered Federal employment laws if the employer (i) relied on and generally followed government standards; (ii) knew of the obligation under the relevant provision; and (iii) attempted to satisfy such obligation by exploring options to comply, implementing interim alternative protections, or following relevant agency guidance.

**Liability for Conducting Testing at Work-Place** – The HEALS Act allows limited liability for employers conducting COVID-19 testing at the workplace for resulting personal injury, except if caused by gross negligence or intentional misconduct.

### Enhancement of COVID-19 Treatment at Nursing Facilities

The HEALS Act sets forth a number of proposals to support nursing facilities, which have especially vulnerable patient populations. When understood with the limits on liability proposed in the Safe to Work Act, nursing homes may be afforded significant liability protection through their compliance with some of the programs described below.

**COVID-19 Strike Teams for Nursing Facilities** – Similar to proposals made by Democrats in the HEROES Act, the HEALS Act authorizes the Secretary to establish and support experienced strike teams to respond to COVID-19-related crises in skilled nursing facilities or nursing facilities that have been assigned a national provider identifier number by the Secretary and executed an agreement to participate in Medicare or Medicaid based on data they report to the CDC. The strike teams would be tasked with such missions as performing medical examinations, conducting COVID-19 testing, and assisting with infection control.

**Promoting COVID-19 Testing and Infection Control in Nursing Facilities** – The HEALS Act would authorize the Secretary, in consultation with the Elder Justice Coordinating Council, to enhance efforts by participating providers during the COVID-19 public health emergency period. Such enhanced efforts would include development of training materials for personnel and enhanced diagnostic testing of visitors, personnel and residents. Thus, participating providers should take note of any trainings made available by the Secretary to ensure compliance with best practices in such areas.



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## Promotion of Domestic Supply Chain for Medical Equipment

**Personal Protective Equipment** – The HEALS Act would require funds appropriated for the Strategic National Stockpile to be used to procure certain personal protective equipment (PPE) only if such items were grown, reprocessed, reused, or produced in the United States, subject to certain exception. It would increase the procurement of domestic PPE for the stockpile with the goal of reaching 100% domestic sourcing as soon as practicable within five years. The bill would also amend the Internal Revenue Code to add a qualifying medical personal protective equipment manufacturing project credit and special rules for transfers of intangible property relating to medical personal protective equipment to United States shareholders. Medical equipment companies that meet the requirements may find increased opportunities to provide personal protective equipment to the stockpile.

**Incentives to Produce Semi-Conductors** – The HEALS Act would establish a program to provide grants to certain entities to incentivize production of semi-conductors. The amount of a grant made pursuant to this section may be not more than \$3 billion and the funds would be restricted to financing the construction, expansion, or modernization of certain facilities and supporting workforce and site development of such facilities. The bill would allow the Secretary to claw back the full amount of a grant if the project is not completed within five years or if, within the applicable term, the entity engages in any joint research of technology licensing effort with the governments of China, Russia, Iran, North Korea, or another foreign adversary that relates to a sensitive technology or product. The bill would initiate a public-private partnership with the Department of Defense to ensure production of advanced, measurably secure microelectronics.

## Scrutiny of Federal Research Funding

The HEALS ACT re-introduces the Safeguarding American Innovation Act bill within the Restoring Critical Supply Chains and Intellectual Property Act. The Safeguarding American Innovation Act was introduced in the Senate on June 18 and seeks to better protect U.S. national and economic security by addressing foreign state efforts involving attacks on basic and other research activities. Ropes and Gray has discussed this bill in previous Alerts, which can be found [here](#) and [here](#).

## Protection of Human Genetic Information

The HEALS Act would require the express, written, informed consent of an individual in order to collect, store, analyze, disseminate, or otherwise use genetic information collected as a result of diagnostic or serologic testing for COVID-19 for any incidental use or any reason other than such diagnostic or serologic testing.

## Additional Proposals

Though not of special interest to the health care and life sciences industries, other bills within the HEALS Act would:

- Expand business meal tax deductions to aid restaurants and restaurant workers (Supporting America's Restaurant Workers Act); and
- Identify critical social contract programs projected to have inadequate balances prior to the end of FY2035 and establish Rescue Committees to address such issues ([The Trust Act](#)).