SENATE REPUBLICANS UNVEIL HEALS ACT, CORONAVIRUS RELIEF PACKAGE

Memorandum

Today, Senate Republicans unveiled the **Health, Economic Assistance, Liability Protection, and Schools** (**HEALS**) Act – a roughly \$1 trillion package intended to provide additional coronavirus relief, support the federal government's coronavirus response, help businesses and schools reopen safely, and stimulate the economy. The package is a compilation of individual bills authored by Republican Committee leaders.

The HEALS Act appears to be a marker bill that stakes out Republicans' starting position in negotiations with Democrats. Earlier today, House Speaker Nancy Pelosi (D-CA) <u>called on</u> congressional Republican leaders and White House officials to negotiate what will likely be the last coronavirus relief package before the November elections. Speaker Pelosi, along with Senate Minority Leader Chuck Schumer (D-NY), are meeting with White House Chief of Staff Mark Meadows and Treasury Secretary Steven Mnuchin this evening. Democrats are expected to push for provisions passed by the House in the Heroes Act (<u>H.R. 6800</u>).

Snapshot – The HEALS Act package includes:

- Senate Finance Package The Senate Finance Committee's American Workers, Families, and Employers Assistance Act (release; text; section-by-section) provides for enhanced unemployment insurance of \$200 per week through September, an additional round of direct payments to individuals (up to \$1,200), employer tax relief, state and local government revenue assistance, and health care provisions to support patients, nursing home residents, and hospitals.
- Senate HELP Package The Senate Committee on Health, Education, Labor and Pensions (HELP) released the Safely Back to Work and Back to School Act (release; section-by-section), which would allow federal student loan borrowers with no income to continue to defer payments and offer additional flexibilities in repayment plans (one-pager); authorize one-time appropriations for states to identify and support scholarship granting organizations in providing "educational freedom scholarships," including for private school tuition and home schooling expenses, when public schools choose not to reopen (one-pager); and support and expand access to child care (one-pager). These are in addition to health care provisions addressing the federal stockpile, diagnostic testing, telehealth, and disease surveillance, which are outlined in more detail below.
- Liability Protections The SAFE TO WORK Act shields individuals, businesses, and health care providers from litigation related to coronavirus exposure, as long as they take reasonable steps to comply with government-issued public health standards and guidance (<u>fact sheet</u>).

- **Buy American** The Restoring Critical Supply Chains and Intellectual Property Act (<u>fact sheet</u>) would require that certain critical medical supplies purchased by HHS for the Strategic National Stockpile be derived from items manufactured domestically.
- **Paycheck Protection Program** Continuing Small Business Recovery and Paycheck Protection Program Act provides \$190 billion for additional loans to small businesses, redefines eligibility from 500 employees to 300 employees, and makes other program changes (<u>fact sheet</u>).
- Appropriations The Additional Emergency Appropriations for Coronavirus Health Response and Agency Operations Act (release; text; summary) provides an additional \$306 billion in discretionary appropriations for government agencies, including \$118.4 billion for the Department of Health and Human Services (HHS).

A summary of the pertinent health-related provisions across the various bills follows:

<u>American Workers, Families, and Employers Assistance Act</u> – Health care provisions at Title III of the Senate Finance bill include:

- Medicare Part B Premium and Deductible at 2020 Levels Section 301 would hold the 2021 Part B premium at the 2020 level for those paying income-related premiums and stipulates that a \$3 surcharge be applied until the resulting SMI Trust Fund shortfall is recouped. The provision aims to prevent an anticipated spike in Part B premium and deductible because of the COVID public health emergency and provider Advance Payment loans.
- **Delayed Repayment of Advance Payment Loans** Section 302 delays the deadline by which hospitals and other providers are required to begin repaying loans under CMS' Advance Payment program until Jan. 1, 2021. The provision also provides more time before the loans must be repaid in full prior to interest being due.
- Authority to Extend Medicare Telehealth Waivers Under section 303, HHS would gain the authority to extend the telehealth flexibilities under section 1135 and the CMS interim final rules through Dec. 31, 2021 even if the public health emergency (PHE) were to end prior to that date. The section does not bind HHS to extending the telehealth policies through that date. A MedPAC evaluation and report on telehealth access, quality, and cost is due by June 15, 2021. HHS is required to provide information on telehealth utilization within three months of enactment and to release a report on such services' impact on access and outcomes (e.g., by physician type, patient demographics, dual-eligible status, diagnosis of COVID or mental or substance abuse disorder, etc.), including recommendations for legislation or administrative action.
- Extension of Medicare Telehealth Flexibilities for FQHCs Section 304 stipulates that the CARES-driven expansion of telehealth for Medicare FQHCs and Rural Health Clinics continues for five years after the public health emergency's expiration.

- Strike Teams for Nursing Facilities Section 312 authorizes HHS to establish Federal strike teams for Medicare- and Medicaid-enrolled nursing facilities, comprised of individuals with relevant skills, qualifications, and experience in responding to COVID-19. Strike teams may perform medical examinations, conducting COVID-19 testing, and assisting facilities with the implementation of infection control practices (such as quarantine, isolation, or disinfection procedures). The Committee intends that these Federal teams will "supplement, not supplant" response efforts carried out by a State strike team or any technical assistance launched by HHS during the emergency period.
- Testing and Infection Control in Nursing Facilities Section 313 authorizes HHS, in consultation with the Elder Justice Coordinating Council (details), to enhance efforts to respond to COVID-19 in nursing facilities by: developing online training courses and training materials for nursing home staff, survey agencies, and the long-term care ombudsman of each State on best practices in infection control and prevention (including cohorting and use of telehealth to mitigate the transmission); and enhancing the diagnostic testing of visitors to, personnel of, and residents of facilities with frequent cases. Specifically, the Secretary is authorized to create an interactive website for this purpose and seek input, as appropriate, from the Elder Justice Coordinating Council and the CDC Director on this training.
- **Transparency in COVID–19 Reporting by Nursing Facilities** Section 314 would require HHS to provide the Governor of each state with a list of all Medicare- and Medicaid-enrolled nursing facilities in which the reported cases of COVID-19 increased during the previous week.
- **Funding for Nursing Homes** Section 315 clarifies that HHS may use amounts appropriated for COVID-19 response under the CARES Act and subsequently enacted legislation, to implement these nursing home provisions. In particular, the summary states that the \$5 billion in Provider Relief Fund dollars <u>announced</u> in July is available for these purposes.
- Allowable Use of Coronavirus Relief Fund Payments by States and Tribal and Local Governments Section 401 under Title IV of the Senate Finance bill would expand the end date for allowable necessary Coronavirus Relief Fund (CRF) expenditures for state, local, and other governments from December 30, 2020 to 90 days after the last day of a government's fiscal year 2021. Additionally, the bill would expand allowable uses of CRF payments to include "revenue shortfalls" relative to fiscal year 2019 levels. See the <u>summary</u> on p. 10 for more details.

Safely Back to School and Back to Work Act – Relevant provisions in the Senate HELP bill include:

• Early Access to Diagnostic Tests – The provisions require HHS to coordinate with CDC and FDA in establishing and publishing policies and procedures for public and private entities to access samples for product development, including diagnostic tests and vaccines. HHS must issue guidance regarding access to such samples.

Under the provision, CDC may enter arrangements with public and private entities to assist in development, validation, and dissemination of diagnostic tests for bio-surveillance and public health response for emerging infectious disease. HHS must consult with manufacturers in determining supply-related needs (e.g., specimen collection and transport materials).

- **On-Shore Manufacturing Capacity for Public Health Emergencies** The provision addresses capacity to support the production of countermeasures (e.g., vaccines and therapeutics) to respond to public health issues. It provides for the implementation of the Medical Countermeasure Innovation Partnership.
- **Improvement of State Stockpiles** The provisions call for the establishment of state stockpiles of medical products and supplies, such as PPE, ventilators, and other equipment. Under the provision, states must submit a stockpile plan to HHS addressing maintenance of the stockpile and preparedness planning, for example.
- Strengthening the Strategic National Stockpile The provision calls for partnerships with manufacturers, distributors, and other entities to increase capacity and reserves of products ahead of public health emergencies.
- Infectious Disease Data Collection The HELP provisions call for the integration of lab testing and epidemiology systems into existing surveillance programs as well as enhanced electronic information exchange among providers, agencies, and public health departments.
- Centers for Public Health Preparedness Ten regional centers would be authorized to assist state and local health departments and others, including through the development of evidence-based practices and preparation of exercises and trainings, among other activities.
- **Telehealth under Employer Plans** Employers would be allowed to cover telehealth as an excepted benefit for employees who do not work full-time or do not qualify for their employer's plan.
- **Protection of Genetic Information** A provision would prohibit the use of genetic information collected incidental to diagnostic or serologic testing without explicit patient consent.

<u>SAFE TO WORK Act</u> – The Safeguarding America's Frontline Employees to Offer Worker Opportunities Required to Kickstart the Economy (SAFE TO WORK) Act does the following:

• Federal Cause of Action – Sec. 121 creates an exclusive federal cause of action that applies to all claims for "person injury caused by, arising out of, or related to an actual, alleged, feared, or potential for exposure to coronavirus." The section would preempt all federal, state, or tribal law, including common law, related to liability for coronavirus exposure, except for laws that impose stricter liability protections. The statute of limitations is one year. The liability limitations apply to an alleged coronavirus exposure that occurred on or after December 1, 2019 and October 1, 2024.

The protection applies to any individuals or entities, including businesses, educational institutions, labor organizations, nonprofit organizations, and state, tribal, or local governments.

• **Requirements for Liability and Safe Harbor** – Sec. 122 requires a plaintiff to satisfy the claim with "clear and convincing evidence" that (1) the defendant did not make "reasonable efforts to comply" with "applicable government standards and guidance"; (2) gross negligence or willful misconduct caused the plaintiff's actual exposure to coronavirus; and (3) the actual coronavirus exposure to coronavirus caused the plaintiff's personal injury.

Notably, an individual or entity would be considered to have made "reasonable efforts to comply" if they follow government standards and guidance that applies to their jurisdiction that conflicts with other government standards and guidance that also applies to their jurisdiction. In other words, an individual or entity would be shielded from litigation if they followed, for example, local government standards and guidance that conflict with federal government standards and guidance. "Applicable government standards and guidance" means "any mandatory standards or regulations" relating to the prevention or mitigation of coronavirus transmission issued by federal, state, or local governments.

The section provides an exception for mandatory standards and regulations. An individual or entity may be held liable if they do not comply with applicable government standards and guidance that are mandatory if they conflict with non-mandatory standards and guidance.

The section further explains that maintaining "written or published policy on the mitigation of transmission of coronavirus" at the time of the claim that complies with applicable government standards and guidance or is more protective than such standards and guidance constitutes "reasonable efforts to comply." However, the absence of a written or published policy does not mean that the individual or entity did not make reasonable efforts to comply.

• Liability Limitations for Health Care Providers – Sec. 141 creates an exclusive federal cause of action for coronavirus-related medical liability action. Similar to the liability limitations for individuals and entities, liability limitations for health care providers would preempt all federal, state, or tribal law, including common law, related to liability for coronavirus exposure, except for laws that impose stricter liability protections. The statute of limitations is one year.

The protection applies to health care providers (including facilities, doctors, nurses, and other licensed health care professionals), volunteers, and administrators (including executives, board members, or other individuals responsible for "directing, supervising, or monitoring the provision of coronavirus-related health care services."

Sec. 142 requires a plaintiff to satisfy the claim with "clear and convincing evidence" that (1) the health care provider committed gross negligence or willful misconduct; and (2) the gross negligence or willful misconduct caused the plaintiff's personal injury.

- **Workplace Testing** Sec. 182 establishes that suits cannot be brought regarding injuries caused during COVID-19 testing at the workplace, unless the injury was caused by gross negligence.
- **Protections for Products** Sec. 201 limits liability for biological drug products and medical devices if they are used within the scope of a Food and Drug Administration (FDA) Emergency Use Authorization (EUA) or meets certain requirements during the public health emergency.

Restoring Critical Supply Chains and Intellectual Property Act

- Domestic Purchasing Requirement for Certain PPE in the Strategic National Stockpile Sec. 102 that any HHS purchases for the Strategic National Stockpile of "covered items" be derived from items manufactured domestically. This stipulates that such supplies be from components grown, reprocessed, reused, or produced in the United States. Covered items include PPE and clothing; sanitizing supplies and ancillary medical supplies such as disinfecting wipes, privacy curtains, beds and bedding, testing swabs, gauze and bandages, tents, tarpaulins, covers or bags; and any other textile medical supplies and textile equipment. The provision includes a purchasing exception if there is not sufficient availability of a covered item, as well as an exception for small purchases (<\$15,000). See further details on p. 1 of the staff-prepared summary here.
- **Investment Credit for Qualifying Medical PPE Manufacturing Projects** Sec. 103 establishes a tax credit that enables qualifying PPE equipment manufacturers to receive a credit of 30 percent for investments in producing PPE, including items in the Strategic National Stockpile. See details on p. 2-3 <u>here</u>, including a limitation on the credit program level to \$7.5 billion.

<u>Additional Emergency Appropriations</u> – The Senate Appropriations bill provides \$306 billion for government agencies overall and \$118.4 billion for HHS, which includes:

- **Public Health and Social Services Emergency Fund (PHSSEF)** \$78.1 billion to the PHSSEF, which is further allocated according to the following:
 - *Provider Relief Fund* \$25 billion in funding for health care providers, on top of the \$175 billion appropriated in previous packages.
 - **Testing** \$16 billion for testing, contact tracing, and surveillance in states. The bill summary notes that this new funding, when combined with the approximate \$9 billion that remains unallocated from the Paycheck Protection Program and Health Care Enhancement Act, would make \$25 billion available for these purposes.
 - **BARDA** \$20 billion for vaccine, therapeutic, and diagnostic development by the Biomedical Advanced Research and Development Authority (BARDA).
 - *Vaccine Distribution* \$6 billion to develop and execute a new COVID-19 vaccination distribution campaign coordinated through CDC. CDC would owe a report to Congress within 60 days containing a comprehensive vaccine distribution strategy.
 - Strategic National Stockpile \$2 billion.
 - *Community Health Centers* \$7.6 billion for HRSA's Health Center Program.
 - *Children's Hospital Graduate Medical Education* \$250 million for the CHGME program to prevent, prepare for, and respond to 11 coronavirus, domestically or internationally.

- *Rural Health Clinics* \$225 million.
- *Poison Control Centers* \$5 million for enhanced capacity at poison control centers.
- *Direct Workers Training* \$5 million
- Centers for Disease Control and Prevention (CDC) \$3.4 billion would be provided to the CDC under the proposal, including \$1.5 billion for state, local, and territorial public health needs; \$500 million to enhance seasonal influenza vaccination efforts; \$200 million for global public health security efforts; and \$200 million to modernize public health data reporting. One provision delineates further that \$1 million in funding shall be used to develop and maintain a data system to be known as the Public Safety Officer Suicide Reporting System, addressing the suicide incidence among public safety officers. The language includes various reporting requirements for the agency to update Congress on the implementation of these activities.
- Centers for Medicare & Medicaid Services (CMS) The bill includes \$150 million for CMS nursing home "strike teams," which are surveying resident and employee safety in skilled nursing facilities (SNFs) and nursing facilities. The agency is directed to provide a report to the Committees on Appropriations 30 days after enactment, outlining a plan for executing strike team efforts, including how safety and infection control measures will be assessed, how facilities will be chosen, and the frequency by which facilities and nursing facilities will be visited.
- Administration for Children and Families (ACF) The bill includes \$16.7 billion for ACF, including: \$1.5 billion for the Low Income Home Energy Assistance Program (LIHEAP) to help low income households pay home heating and cooling bills; \$5 billion for the Child Care and Development Block Grant, including direct support for child care providers; \$10 billion in Back to Work Child Care Grants; and \$190 million for family violence prevention and child welfare programs.
- Administration for Community Living (ACL) \$75 million. The proposal provides \$75 million for services targeted to older Americans and the disability community, including caregiver support, protection and advocacy, and home and community based support services.
- National Institutes of Health (NIH) The bill provides a total of \$15.5 billion for the NIH, including nearly \$481 million to the National Institute of Allergy and Infectious Diseases and \$200 million for the National Institute of Mental Health.

On p. 70-72, the bill includes \$12.9 billion for the Office of the Director, including \$10.1 billion for reopening labs that lost productivity during the pandemic; \$1.24 billion for the ACTIV public-private partnership focused on COVID vaccines and therapeutics; \$240 million to supplement training awards and extensions; and \$1.3 billion for COVID-specific research at smaller centers.

The bill stipulates that NIH contract with the National Academics to develop a framework for equitable distribution of COVID vaccines, with the National Academics reporting to ACIP by Sept. 18, 2020.

• Substance Abuse and Mental Health Services Administration (SAMHSA) – The bill provides \$4.5 billion for SAMHSA, including \$2 billion for the Mental Health Services Block Grant. It stipulates that 50 percent of that block granted amount go to behavioral health providers. Among

other funding (see p. 73), the bill provides \$600 million for the Certified Behavioral Health Clinic Expansion Grant program and \$250 million for flexible emergency grants to states.

- General Provisions Beginning on p. 96, General Provisions under the bill do the following:
 - Waive certain hiring restrictions for coronavirus appointments.
 - Provide flexibility for contracts related to coronavirus work.
 - Exempt restrictions for premium and overtime pay for employees performing coronavirus-related work.
 - Provide flexibility for the Secretary to transfer funds between agencies with the exception of the Provider Relief Fund and testing, contract tracing, and surveillance funds.
 - Provide \$6 million for the Office of the Inspector General for oversight activities.
 - Extend the obligation period for FY 2015 NIH grants through FY2021.
 - Make a technical correction to the CARES Act to allow Community Services Block Grant funds to be allocated to all states as intended.

We hope this information is helpful. Please reach out if you have any questions.