BIPARTISAN CONNECT FOR HEALTH ACT OF 2021 SEEKS TO PERMANENTLY EXPAND TELEHEALTH REIMBURSEMENT

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Health Care and FDA Alert

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On 29 April 2021, Senator Brian Schatz (D-HI) reintroduced the Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2021, S. 1512 (the Act).[1] The bill, which currently has 59 cosponsors in the Senate,[2] aims to codify the expanded access to telehealth services provided by the current Section 1135 waivers due to the COVID-19 public health emergency (PHE), in addition to other measures that support the provision of telehealth care.

BACKGROUND AND CONGRESSIONAL FINDINGS

Senator Schatz has introduced the Act in some form each session since 2016, with the stated goal of reducing barriers to accessing telehealth services.[3] This year, however, the effort is buoyed by over a year of patients accessing quality care via telehealth technology under the current Section 1135 waivers, strengthening the case for permanent change. The findings in the Act acknowledge the value of telehealth services, including expanded access to health care, improved quality of care, reduced costs, and the strengthening of health care workforce expertise. The successful expansion of telehealth services during the COVID-19 PHE appears to have also heavily influenced the revised bill. In particular, the bill specifically states that the COVID-19 PHE demonstrated the benefits of telehealth, including reducing risk of infection for patients and providers and conserving space in facilities, and notes that the Centers for Disease Control and Prevention has recommended that "telehealth services should be optimized, when available and appropriate, during the pandemic."[4]

REMOVING BARRIERS TO TELEHEALTH COVERAGE

The Act, which is also supported by over 150 advocacy and health organizations, acknowledges that practitioners can provide high-quality telehealth services in a safe and effective manner. As such, the legislation primarily seeks to promote higher quality of care, expanded access to telehealth services, and reduced Medicare spending through relaxation of current reimbursement rules and thus expanded coverage of additional telehealth services.

Specifically, the Act would amend the Social Security Act to promote the continued expansion of telehealth services by providing for the following:

- Permanently removing all geographic restrictions on telehealth services;

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- Expanding the definition of originating site to include the home of an individual and granting the Department of Health and Human Services (HHS) Secretary additional flexibility to establish other locations as originating locations where deemed appropriate;
- Removing restrictions on the use of telehealth in emergency medical care;
- Permanently adding federally qualified health centers and rural health clinics as eligible distant site providers;
- Removing restrictions on the use of telehealth services at Indian Health Service and Native Hawaiian health care system facilities;
- Allowing for recertification of hospice beneficiaries via telehealth.
- Permitting temporary coverage of certain telehealth services in order to determine the potential benefit of covering such telehealth services permanently; and
- Requiring revisions to current processes to add telehealth services in order to prioritize the addition of services that provide improved access to care.

The Act provides the HHS Secretary with permanent authority to waive certain requirements for Medicare reimbursement of telehealth, including limitations on qualifying originating sites, geographic location requirements, the type of technology used, the types of practitioners that can furnish telehealth services, and the types of services provided via telehealth, subject to a finding that such waivers would adversely impact quality of care. The Act requires the implementation of processes for public comment and periodic review and reassessment of such waivers, as well as public reporting on the impact and number of beneficiaries benefitting from the waivers.

Note that the expansion of Medicare reimbursement under the Act does not otherwise preempt licensure or geographic, technology or patient informed consent requirements that individual state licensing boards and other regulatory authorities may impose on licensed practitioners or change whether the appropriate standard of professional care is able to be met through a telemedicine encounter.

PROGRAM INTEGRITY

The Act includes multiple provisions to ensure program integrity by providing additional funding to the HHS Office of Inspector General (OIG) for oversight of telehealth services through audits, investigations, and other oversight and enforcement activities. In addition, the Act establishes that the provision of technology to Medicare beneficiaries for the purpose of telehealth services, remote patient monitoring, and other digital health services is not considered “remuneration” under the prohibition on beneficiary inducements provision of the Civil Monetary Penalties Law, provided certain conditions are met. Finally, the Act requires the HHS Secretary to make available provider and beneficiary education resources on telehealth, including on reimbursement requirements, telehealth-specific privacy and security, and telehealth utilization to engage and support underserved and high-risk populations.

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DATA AND TESTING OF MODELS

The Act requires the HHS Secretary to collect and analyze qualitative and quantitative data on the impact of telehealth services and other services utilizing digital health technology permitted under the Section 1135 waivers and provided under alternative payment models and to report to Congress on the conclusions resulting from the collection and analysis of such data. Finally, the Act authorizes testing models to evaluate allowing additional health care practitioners to provide telehealth services and encourages the Centers for Medicare & Medicaid Services Innovation Center to develop and test telehealth models under the Medicare program.

K&L Gates' FDA and health care practices regularly assist life sciences, technology, and health care companies on the implementation of innovative digital health services such as telemedicine. We will continue to closely monitor this bill and related government agency developments regarding the adoption of telemedicine rules and regulations.

FOOTNOTES

[1] *See* CONNECT for Health Act of 2021, S. 1512, 117th Cong. (2021), https://www.congress.gov/bill/117th-congress/senate-bill/1512/text?loclr=cga-bill.

[2] *See id*, https://www.congress.gov/bill/117th-congress/senate-bill/1512/cosponsors?r=1&s=7&searchResultViewType=expanded.

[3] Representative Mike Thompson (D-CA-5) has introduced the House of Representatives counterpart, where it is currently under review by multiple committees. See CONNECT for Health Act of 2021, H.R. 2903, 117th Cong. (2021) *To amend title XVIII of the social Security Act to expand access to telehealth services, and for other purposes,* https://www.congress.gov/bill/117th-congress/house-bill/2903?=%7B%22search%22%3A%5B%22Mike+thompson%22%5D%7D&s=1&r=3.

[4] *Id* § 2(a)(7).

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