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Memorandum

Date: April 17, 2018

From: Holland & Knight

To: Interested Healthcare & Life Sciences Clients

Re: Federal Telehealth Policies

On Feb. 9, 2018, Congress passed and President Donald Trump signed into law the Bipartisan Budget Act of 2018 (BBA). This wide-reaching legislation enacts major changes for telehealth policy in Medicare by incorporating policies from the Senate's Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act. These policy changes from the CHRONIC Care Act represent the most significant legislative advances for Medicare's telehealth policy in several years.

Building on those changes, a bill is expected to be drafted in the House Committee on Ways and Means seeking to widen telemedicine coverage under Medicare to help reduce unnecessary hospital visits by Medicare patients. The legislation would expand the coverage of telehealth services under Medicare with the goal of reducing expensive, unnecessary hospital visits.

These developments suggest that we can expect further emergence of telehealth solutions by Congress. Lawmakers are targeting telehealth for its potential to reduce healthcare costs and advance population health management. Given the growing developments in this space, please see a detailed overview below of the 2018 congressional and regulatory developments around telehealth.

I. Advances for Telehealth in the Bipartisan Budget Act (BBA) of 2018

A. Medicare Advantage (MA) Plans

- Beginning in plan year 2020, the BBA allows MA plans to offer additional, clinically appropriate telehealth benefits in their annual bid amount beyond the services that receive payment under traditional Medicare. The U.S. Department of Health and Human Services (HHS) Secretary is required by Nov. 30, 2018, to solicit comments on the types of telehealth services and the requirement of the related benefits, such as remote patient monitoring, secure messaging, and store and forward technologies. MA plans would be required to provide access to services offered via telehealth through in-person visits as well, allowing patients the choice between both options.
- These new provisions go into effect in 2020, so now is time to engage MA plan partners in discussions on how to amend their participation agreement and cover telehealth services (e.g., remote patient monitoring, secure messaging, store and forward technologies, and other non-

face-to-face services). Some of these services should be considered to be an "additional telehealth benefit" (meaning, eligible to be counted as part of the basic benefit package). HHS will also solicit comments on the requirements for providing and furnishing such telehealth services (e.g., training and coordination rules).

B. Accountable Care Organizations (ACOs)

- The BBA enables ACOs to expand the use of telehealth by allowing other ACOs to take advantage of the existing Next Generation ACO telehealth waiver, which waives the geographic location criteria, allows the patient's home to serve as the originating site, and allows for the use of teledermatology and teleophthalmology. Now this waiver can be used in the Medicare Shared Savings Program (MSSP) Track II, MSSP Track III and other two-sided risk ACO models with prospective assignments that are tested or expanded through the Center for Medicare & Medicaid Innovation.
- No facility fee will be paid; only the professional service is paid pursuant to this telehealth expansion. Coverage does not extend to services appropriate only for hospital inpatients.

C. TeleStroke and End-Stage Renal Disease (ESRD)

- Currently, Medicare will only cover telehealth services that are provided to patients located in certain rural or nonurban areas. However, under the new law patients arriving at a hospital with acute stroke symptoms may receive a telehealth consultation to determine the best course of treatment, without regard to their geographic location. This provision goes into effect Jan. 1, 2019.
- Medicare patients with end-stage renal disease (ESRD) on home dialysis may receive their monthly clinical assessments at home using telehealth, rather than in-person, beginning Jan. 1, 2019. This provision allows freestanding dialysis facilities and the patient's home to serve as the originating site and eliminates geographic restrictions for all originating sites. Patients will be required to receive a face-to-face visit for the first three months of home dialysis and once every three months thereafter. In certain circumstances, providers will be allowed to furnish equipment to help facilitate telehealth to patients receiving home dialysis.

II. Creating Opportunities Now for Necessary and Effective Care Technologies for Health Act (CONNECT Act, S. 1016/H.R. 2556)

- The CONNECT Act seeks to expand access to telehealth by making a series of exceptions to the restrictions around telehealth currently in Medicare, including the originating site, geographic, provider and service restrictions for ACOs, waivers, mental health services, Medicare Advantage, and bundled and global payments. It also allows for the reimbursement for remote patient monitoring services when they are in combination with chronic or transitional care management services. Additional sections eliminate some of the geographic or originating site restrictions on Federally Qualified Health Centers (FQHCs) facilities operated by Indian Health Services, stroke care and ESRD services.
- Sections 2-5 contain similar provisions to the CHRONIC Care Act and were included in the Bipartisan Budget Act (BBA) of 2018 as described above.

III. Access to Addiction Treatment via Telemedicine (Congressional Opioid Legislation)

- ***Improving Access to Remote Behavioral Health Treatment***
  - Written by Reps. Doris Matsui (D-Calif.) and Gregg Harper (R-Miss.) and considered as part of the Energy and Commerce hearing on the opioid crisis.
  - Would amend the Controlled Substances Act that bans the delivery, distribution and dispensing of certain drugs online without a valid prescription.
  - Requires the U.S. Drug Enforcement Administration (DEA) to register community mental health or addiction treatment centers as eligible patient site for initial controlled substances prescription.

- ***Special Registration for Telemedicine Clarification Act of 2018***
  - Written by Reps. Buddy Carter (R-Ga.) and Rep. Cheri Bustos (D-Ill.) and considered as part of the Energy and Commerce hearing on the opioid crisis.
  - The legislation will clarify telemedicine waivers. Specifically, the legislation would instruct the Attorney General to take necessary steps to allow for the prescription of medication-assisted treatment (MAT) and other controlled substances via telemedicine. In 2008, Congress strengthened prohibitions against distributing and dispensing controlled substances by passing the Ryan Haight Online Pharmacy Consumer Protection Act (P.L. 110-425). The Ryan Haight Act made it illegal for a practitioner to dispense controlled substances through the internet without at least one in-person patient evaluation in order to prevent fraud and abuse. The law allows the Attorney General to create a special registration through which healthcare providers may prescribe controlled substances via telemedicine in emergency situations, such as a lack of access to an in-person specialist. However, the special registration was never implemented. The Special Registration for Telemedicine Clarification Act directs the Attorney General, with the Secretary of Health and Human Services, to promulgate the necessary regulations within 90 days to implement this special registration.

- ***Opioid Crisis Response Act of 2018***
  - The Senate HELP bill requires the DEA to create a regulation allowing for the issuance of a special registration to enable practitioners to engage in telemedicine for prescribing controlled substances without a prior in-person exam. The bill would require this regulation to be issued within one year of passage.
  - The second telemedicine policy change in the Act would specifically allow community mental health and addiction treatment centers to register with the DEA to administer controlled substances through the practice of telemedicine.

- With congressional activity ramping up and evolving legislation under consideration in both House and Senate, it may be likely that an opioid package advances in Congress this year. Both House and Senate Committee leadership have suggested that they aim to mark-up bipartisan opioid legislation before the summer. It is noteworthy that both committees have included similar telemedicine proposals, which may help to support their inclusion as part of an opioid package should such legislation be enacted into law.

IV. Proposed Medicare Telehealth Legislation

- ***HR 2550: Medicare Telehealth Parity Act***
  - Introduced by Rep. Mike Thompson (D-Calif.)
  - The bill failed during its first introduction in 2015, but is now getting support from the Congressional Telehealth Caucus. The Congressional Telehealth Caucus was launched last May by Thompson, alongside Reps. Gregg Harper (R-Miss.), Diane Black (R-Tenn.) and Peter Welch (D-Vt.).
  - The first phase would expand qualifying originating sites to include all FQHCs and all rural health clinics, and expand qualifying geographic locations to include counties in Metropolitan Statistical Areas of fewer than 50,000 residents. It would also expand telehealth coverage to include services offered by certified diabetes educators, respiratory therapists, audiologists, occupational therapists, speech language therapists and physical therapists. Finally, it would compel Medicare to cover asynchronous (store-and-forward) telehealth services across the country, not just in Alaska and Hawaii.
  - The second phase would add the home to the list of qualifying originating sites, and expand qualifying geographic locations to include counties in Metropolitan Statistical Areas with populations of between 50,000 and 100,000.
  - The third phase would add counties in Metropolitan Statistical Areas with populations above 100,000 to the list of qualifying geographic locations. It would also authorize the Centers for Medicare & Medicaid Services (CMS) to develop and implement new payment methods for telehealth services.

- ***HR 2291: Helping Expand Access to Rural Telemedicine (HEART) Act***
  - Introduced by Rep. Sean Duffy (R-Wis.)
  - The bill aims to improve access to telehealth in rural parts of the country and expand remote patient monitoring programs for people with chronic obstructive pulmonary disease (COPD) and congestive heart failure.

- ***HR 3360: Telehealth Enhancement Act***
  - Introduced by Reps. Mike Thompson (D-Calif.) and Gregg Harper (R-Miss.)
  - The bills aims to expand the list of healthcare sites eligible for Medicare reimbursements for telehealth to include urban critical access hospitals, sole community hospitals, home telehealth sites and counties with populations of fewer than 25,000 people.

V. Other Federal Developments

- **The Ways and Means Committee** is drafting legislation that would expand the coverage of telehealth services. The bill has yet to be completed. Notably, it will include demonstration language from Section 13 of the CONNECT Act – an HHS evaluation and report on the use of telehealth and remote patient monitoring under all demonstration programs and pilots with a telehealth waiver.

- **The Reaching Underserved Rural Areas to Lead on Telehealth (RURAL) Act (S. 1377)** seeks to allow nonrural classified health systems to qualify for discounts in the Federal Communications Commission's Healthcare Connect Fund as long as the money goes toward broadband services that would help people in rural areas.
- ***The Hallways to Health Act*** **(S. 356/H.R. 1027)** aims to boost telehealth services in schools by connecting them with community health centers, providing more avenues for reimbursement and creating a demonstration project to expand telehealth access in schools and in medically underserved areas.

VI. FCC – Rural Health Care Program/Broadband Connectivity

- The Healthcare Connect Fund (HCF) Program provides a 65 percent discount on eligible expenses related to broadband connectivity to both individual rural healthcare providers (HCPs) and consortia, which can include nonrural HCPs, if the consortium has a majority of rural sites.
- The FCC released a proposal to increase funding for the agency's Rural Health Care Program, which is capped at $400 million each year. It would waive the Rural Health Care Program's cap on a one-time basis and instruct the Universal Service Administrative Co. (USAC) – an independent nonprofit designated by the FCC – to carry over unused program funds from prior years.
- Recently, the USAC announced that it will cut funding by more than 15 percent for individual RHC applicants and 25 percent for consortium applicants for Funding Year 2017 (FY2017). The announced funding cuts were much larger than the 7.5 percent reduction for FY 2016 and were announced over eight months into the funding year. These severe cuts in funding effectively impose retroactive rate increases on healthcare providers who have been receiving service from July 1, 2017.

VII. Other Federal Agencies

- **CMS-2018 Medicare Physician Fee Schedule Changes**

    - The Calendar Year (CY) 2018 Medicare Physician Fee Schedule (MPFS) included the expansion of telehealth services. CMS added the following codes to the list of covered telehealth services for 2018:
        - HCPCS code G0296: visit to determine low-dose computed tomography eligibility
        - CPT code 90785: interactive complexity
        - CPT codes 96160 and 96161: health risk assessment
        - HCPCS code G0506: care planning for chronic care management
        - CPT codes 90839 and 90840: psychotherapy for crisis
    - CMS also unbundled CPT code 99091 in 2018, meaning that providers will be able to be reimbursed separately for time spent on collection and interpretation of health data that is generated by a patient remotely, digitally stored and transmitted to the provider, at a minimum of 30 minutes of time. CMS stated that this is a first step toward recognizing remote patient monitoring services for separate payment, and it will continue to closely

track the American Medical Association's (AMA) CPT Editorial Panel activities as they further refine and value the code sets for remote monitoring.

- The agency also requested information on ways they can expand telehealth services without a law change, particularly around remote patient monitoring.
- CMS, through its physician fee rulemaking process, determines which telehealth services meet the conditions for coverage and payment under Medicare. In each cycle, CMS allows the public to request and comment on proposed telehealth services to include for consideration on its Medicare coverage list. For the CY 2018 cycle, the public submitted comments from July 13, 2017, to Sept. 11, 2017. The requests for telehealth services that CMS deems as "qualifying" in the CY 2018 cycle will be discussed for rulemaking in the CY 2020 cycle.

- **Office of the Inspector General (OIG)**

  - Under the first project, OIG will review Medicare claims paid for telehealth services provided at distant sites that do not have corresponding claims from originating sites to determine whether those services met Medicare requirements. An eligible originating site must be the practitioner's office or a specified medical facility, not a beneficiary's home or office. This project is underway and is expected to be completed in 2018.
  - Under the second project, OIG will determine whether states' Medicaid payments for services delivered using telecommunication systems were allowable in accord with Medicaid requirements. Medicaid pays for telemedicine, telehealth and telemonitoring services delivered through a range of interactive video, audio or data transmission (telecommunications). Medicaid programs are seeing a significant increase in claims for these services and expect this trend to only continue.

- **U.S. Department of Veteran's Affairs (VA)**

  - The agency is preparing to overhaul its approach to telehealth licensure by overriding state restrictions either through rulemaking or through legislation (VETS Act) which will help expand telehealth initiatives.