ML STRATEGIES

Health Care Update & Telehealth Policy Alert

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In the previous Congress, we saw a burst of policy and industry attention to telehealth as lawmakers and stakeholders alike recognized the cost, quality, and accessibility benefits of telehealth. In the first few months of the 114th Congress, we have seen the momentum for policy to address telehealth continuing, if not increasing in pace.

Congressional Progress

SGR and Telehealth: In April, Congress passed the **Medicare Access and CHIP Reauthorization Act of 2015**, also known as the Sustainable Growth Rate (SGR) repeal, which addressed several aspects of telehealth policy. The legislation included Merit Based Incentive payments, the use of telehealth for timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth as a means of care coordination. It also directed the Government Accountability Office (GAO) to study and report on the use of telehealth in federal programs and in remote patient monitoring services, including:

1. How the definition of telehealth across various federal programs and federal efforts can inform the use of telehealth in the Medicare program;
2. Issues that can facilitate or inhibit the use of telehealth under the Medicare program;
3. Potential implications of greater use of telehealth with respect to payment and delivery systems; and
4. How CMS monitors payments made under the Medicare program to providers of telehealth services.

21st Century Cures Initiative: On the House side, the Energy and Commerce Committee's 21st Century Cures Initiative targets telehealth, albeit in a more limited fashion than many stakeholders would prefer. Section 3021 of the legislation includes non-binding, "sense of the senate" language requesting the cooperation of state medical boards to coordinate practitioner licensing, and directs CMS and the Medicare Payment Advisory Commission (MEDPAC) to conduct various studies and produce reports on barriers to wider telehealth use.

Many stakeholders and advocates — including the American Telemedicine Association (ATA) — had hoped that the ***21st Century Cures Act*** would ultimately make more significant and meaningful strides toward expanding Medicare telehealth payments, resolving licensure issues, and defining telehealth clinical guidelines. However, efforts on telemedicine policy reform are ongoing outside of the 21st Century Cures Act.

Despite the omission of substantive telehealth provisions in the 21st Century Cures Act, Representative Doris Matsui (D-CA), a member of the Energy and Commerce (E&C) Bipartisan Telemedicine Member Working Group, clarified during the Subcommittee on Health's markup of the bill that the Committee's work is not finished when it comes to telehealth. The telehealth provisions in the legislation are "designed to be an on-ramp to the ongoing effort of the working group," Matsui said. Additionally, she said that the telehealth provisions included in the legislation are "not a replacement for our larger effort that will get to ways to expand Medicare reimbursement for telehealth."

We understand that there is an effort underway on the E&C Committee to develop stand-alone legislation — and that conversations and negotiations are underway and ongoing. A primary focus would be developing potential policy options that the Congressional Budget Office (CBO) could review and determine to have a budgetary saving. This is a critical component, as previous versions of telehealth legislation have been scored by CBO to have very high costs due to increased Medicare utilization — a significant complexity that needs to be overcome in order to move legislation in this Congress.

Senate Progress: Meanwhile, the Senate is proceeding with its own version of the 21st Century Cures Initiative at a more measured pace. A group of Senators — Brian Schatz (D-HI), Roger Wicker (R-MS), John Thune (R-SD), and Thad Cochran (R-MS) — have joined together to draft a telehealth bill which seeks to increase Medicare telehealth reimbursement. The group has begun work with the Congressional Budget Office (CBO) to find telehealth coverage options that will produce savings in order to reach a final bill that does not need additional pay fors. Speaking at a Senate Commerce Subcommittee on Communications, Technology, Innovation, and the Internet **hearing** on the issue, Schatz said that Medicare telehealth policies are "lagging significantly" and pointed to the Veterans' Health Administration (VHA) as proof that telehealth reimbursement can yield successful outcomes — the VHA's home

telehealth program reduced hospital stays and decreased admissions.

Schatz's efforts build on the long track record of his colleagues on telehealth. In the 113th Congress, Senators Wicker and Cochran introduced **The Telehealth Enhancement Act of 2014**, a Senate companion measure to legislation introduced by Representative Greg Harper (R-MS) in the House to extend telehealth coverage for critical access and sole-community hospitals. Wicker's office has said that this bill could be incorporated into the group's work on its telemedicine bill. Senator Thune has been a supporter of telehealth for years — including sponsoring the Fostering Independence Through Technology (FITT) Act, introducing amendments to promote remote monitoring, and advocating for telehealth to be included in Medicare alternative payment models.

Finally, telemedicine and remote monitoring will be a focus of the Senate HELP Committee moving forward. Chairman Lamar Alexander (R-TN) and the HELP Committee will likely focus on Electronic Health Records (EHRs) as part of the Senate's version of the 21st Century Cures initiative. Chairman Alexander has recently said that the version of that measure that he and the Committee are developing will go "more in depth" than the House Energy and Commerce Committee to fix problems with the EHRs, built up with $30 billion in federal incentive programs. A special workgroup, which includes Sen. Alexander and HELP Ranking Member Patty Murray (D-WA), has been meeting weekly with staff from the Office of the National Coordinator for Health Information Technology (ONC) and the office of NIH Director Francis Collins to identify ways to improve EHRs.

Chronic Care Working Group: Another effort in the Senate is being led by Senators Mark Warner (D-VA) and Johnny Isakson (R-GA), who are collaborating on a bipartisan working group to explore solutions to improve Medicare outcomes for chronic care patients. As part of the effort, the senators are seeking input on how telehealth and remote monitoring could further "strengthen care coordination and effectively provide quality chronic care." Stakeholder comments are due to this working group by Monday, June 22.

Efforts within the Administration

Within the Administration, several federal agencies have tackled various aspects of telehealth in recent months.

CMS: In March, the Centers for Medicare & Medicaid Services (CMS) unveiled its newest accountable care organization (ACO) program called the "Next Generation ACO" through the CMS Innovation Center. The announcement stated that the new ACO model would have flexibility around Medicare telehealth rules, thus allowing ACOs to utilize the technology regardless of a patient's geographic location. If passed, the SGR legislation could open the door for CMS to test telehealth payment in more than just a limited number of models currently being implemented.

USDA: The U.S. Department of Agriculture (USDA) has **announced** $19 million in fiscal year 2015 funding for the Distance Learning and Telemedicine (DLT) grant program. DLT provides increased access to education, training and health care resources in rural areas, including financing telecommunications equipment, computer networks and advanced technologies for use by students, teachers, medical professionals and rural residents.

FDA: In February, the Food and Drug Administration (FDA) released **final guidance** dealing with the regulatory treatment of Medical Device Data Systems (MDDS), which are hardware or software products that transfer, store, convert formats, and display medical device data. Of note, the FDA stated it will not enforce regulations — including registration and listing, premarket review, and post market reporting — for low risk devices. While this guidance loosens restrictions on certain hardware and software, it also clarifies that "active patient monitoring" devices fall outside the scope of MDDS and are regulated separately.

FTC: The Federal Trade Commission (FTC), as part of a staff report titled **"Internet of Things: Privacy & Security in a Connected World**," outlined the agency's recommendations for regulating devices and products which are interconnected through the Internet and which can send and receive data. As telehealth utilizes devices and technologies which fall under the board category of Internet of Things, the report highlights the need for cyber protections and other means of securing health privacy.

Conclusion

Moving forward, the amount of activity taking place in just the first few months of the 114th Congress likely sets the stage for even more policy advances in telehealth. Given the amount of activity taking place, we have put together this alert to highlight current opportunities for stakeholders to consider. We are available to discuss the contents of this alert further and to answer any questions.

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Alex Hecht is a trusted attorney and policy strategist with over 20 years of experience advising clients across a broad range of industries on how to navigate complex policy environments. His strategic insight and hands-on experience in both legislative and regulatory arenas empower clients to advance their priorities with clarity and confidence in an evolving policy landscape.

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