DHIT
DIGITAL HEALTH IMPACT + TRANSFORMATION

Digital Health Technology
Legislative & Policy Update

Welcome to DHIT's second North Carolina legislative and policy update. We intend this quarterly newsletter to be your comprehensive update of all legislative and policy developments related to Digital Health. We will also update you on our efforts to develop a thriving Digital Health ecosystem in our state. In what follows, you will find a summary of legislative activity over the last several months, a summary of our efforts to engage policy makers, an update on federal developments, and a brief overview of what other states are doing in the digital health arena.

North Carolina Legislative Summary

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Over the last several months, members of the North Carolina General Assembly have been conducting committee hearings on a fairly regular basis. Committees overseeing the Department of Health and Human Services, the Economic Development and Global Engagement Committee and others have held several meetings. Digital Health technologies were discussed in the form of a report from Secretary Mandy Cohen dealing with the current state of telemedicine in North Carolina. This report was mandated in a "study bill" (House 283) referenced in our last update. The report can be found here.

Federal Policy Developments

The consensus out of Washington seems to be that Federal efforts will focus on managing healthcare costs. To the extent that digital health can achieve that goal, policy makers should be favorably disposed. For an assessment of what might be in store at the federal level see this interesting report from "Mobil Health News".

Also of note, last fall the FDA announced three new guidelines involving digital health technology. These guidelines are a follow up to the FDA's Digital Health Innovation Action Plan issued last summer. Two of the guidelines were in draft form and the third was final. The first, outlines the FDA's guidelines for the use and development of Clinical and Patient Decision Support Software. The second, Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act, addresses a number of digital health matters related to the "Cures" act. The third guidance comes in final form and is called Software as a Medical Device: Clinical Evaluation. This document establishes common principles for regulators to use in evaluating the safety, effectiveness and performance of software as a medical device. These FDA guidelines are important because they have a significant impact on the investment in, and development of, digital health solutions.

Finally, for an interesting take on the future role of the federal government in digital health technology, see the article by the Bipartisan Policy Center called, "The Future Role of Government in Health Information Technology and Digital Health. It can be found at https://bipartisanpolicy.org/library/health-it-and-digital-health/

VISIT DHITGLOBAL.ORG FOR DIGITAL HEALTH-RELATED NEWS, VIEWS AND EVENTS.

## DHIT Working to Shape Digital Health Policy In North Carolina

As we noted in our October update, there is a lot of interest in digital health among North Carolina policy makers. General Assembly members and other policy makers are interested in how digital health technologies can improve patient outcomes and save healthcare costs in both the Medicaid program and the State Health Plan. Unfortunately, these policy makers have only a vague idea what digital health technologies are or how they can be employed. Since our October update, DHIT lobbyists have been working hard to change this situation.

DHIT staff and Anthony Solari, our lobbyist, have met with over two dozen key members of the General Assembly in an effort to inform them about the benefits that digital health can bring for patients, our state's economy, and for taxpayers. In addition, legislators have participated in DHIT events. Representatives Verla Insko and Graig Meyer both attended our December Happy Hour at Launch Chapel Hill featuring a reverse pitch by investors from across the region. DHIT staff have also met with policy makers at the Department of Commerce and the Department of Health and Human Services.

In May, DHIT staff and NC policy makers will be meeting with Digital Health advocates from Massachusetts who drafted and helped to pass that state's landmark $10 billion investment in life sciences. Finally, DHIT staff and our lobbyists are working with policy makers to craft legislation that will help foster a vibrant digital health ecosystem in North Carolina. We expect this legislation to be introduced during the 2019 legislative session.

This work is just the beginning of DHIT's efforts to impact public policy in ways that will help to foster a vibrant digital health economy in North Carolina.

NUMBER OF DEALS BY GEOGRAPHY
H1 2017

ROCK HEAL+H

LEGEND

$500M+
$100-500M
$50-100M
$10-50M
> $0-10M
# of deals in metro area
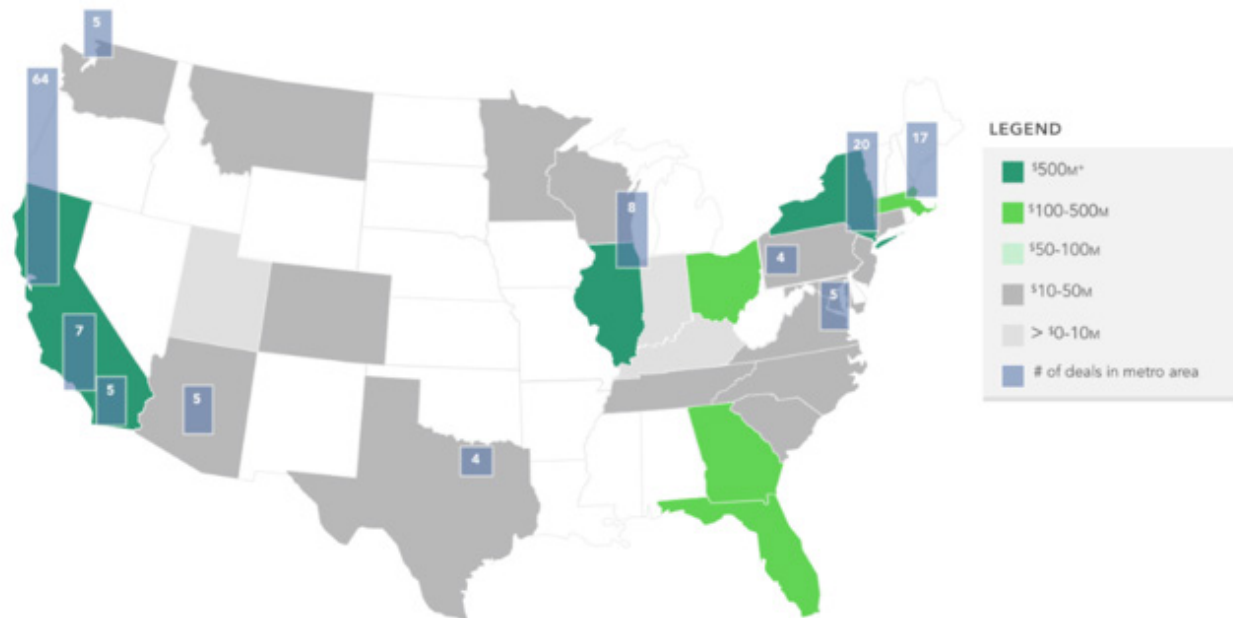
Source: Rock Health Funding Database
Note: Only includes U.S. deals >$2M, data through June 30, 2017

[1] Source: Digital Health Funding 2017 Midyear Review: A Record Breaking First Half. By Halle Tecco and Megan Zweig. In Rock Health. https://rockhealth.com/reports/2017-mid-year-funding-review-a-record-breaking-first-half/#geographies

[2] Ibid.

DIGITAL HEALTH: The National Scene

In the policy arena, digital health technologies are most often seen as one component of a much larger "biotechnology" or "life science" ecosystem. While this is, in one sense, true, the characterization is misleading. It would be more accurate to say that "digital health technologies" are the common factor driving today's various "life science" and "biotechnology" initiatives.

Much of the public policy enacted over the last 10 years has been designed to promote "biotechnology" or "life sciences" industries broadly defined. As such, it is not clear just how much of this effort is specifically directed toward digital health technologies.

Some guidance as to where digital health ecosystems may be receiving support in the public policy arena can be gleaned by looking at where investment dollars have gone. During 2017, New York and Illinois joined California among states with the highest amount of private investment ($500+ million). Florida, Georgia, and Massachusetts all had between $100 and $500 million in private investments. Among cities, San Francisco, Cincinnati, Bethesda, Miami, Milwaukee, Nashville and St. Cloud led the way. The map below provides a visual summary of where investment dollars have gone. It is no accident that these same states are often cited as leading the charge in fueling public policy related to Digital Health Technologies.

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Recent Developments Related to Digital Health

During 2017, many states updated their telemedicine statutes. In most cases, these changes were designed to better define regulatory frameworks affecting the remote delivery of care. This article by Mobil Health News provides a concise summary.

Massachusetts continued to further its investment in healthcare technology with a $250,000 contribution to the Massachusetts Digital Health Initiative, with the money going to the program's Digital Health Innovation Laboratories. Many states continued to take steps designed to further the use and integration of health IT systems. Some states, including Minnesota and Massachusetts, enacted mandates for the use of health IT tools. States continued to focus on planning, protecting privacy, financing, and promoting health exchange information.

Starting in 2008, a number of states began enacting laws to promote or otherwise encourage the growth of biotechnology, life sciences and digital health technologies. These incentives come in the form of tax breaks, legislative declarations of support, funds for financing research, establishing biotechnology or life science centers, issuing bonds to support the ecosystem, establishing study commissions, and other measures. Among those that have enacted policy specifically devoted to the life or biosciences are: Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Kansas, Louisiana, Maine, Massachusetts, Maryland, Michigan, Minnesota, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Pennsylvania, Rhode Island, Texas, and Virginia.

It is important to note, however, that there are great differences in the amount of support among these states. Among them, California, Massachusetts, New York, and perhaps Colorado are heads and shoulders above the others in the support they provide.

North Carolina has all the components needed to be a national leader in Digital Health. It's time for NC policy makers to step up and help us foster a vibrant Digital Health ecosystem in our state.

Key Legislative Appropriations and Policy Making Committees

House Appropriations, Health and Human Services. Chairs: Reps. Brisson, Dobson, Malone, Murphy.

House Commerce and Job Development. Chairs: Reps. Conrad, Martin, Ross.

House Appropriations Committee. Senior Chair: Rep. Dollar, Chairs: Arp, Burr, Faircloth, Johnson, Lambeth, McGrady.

Senate Appropriations Base Budget: Chairs: Senators Brown, Harrington, Jackson.

Senate Appropriations On Health and Human Services. Chairs: Senators Hise, Krawiec, Pate.

Senate Commerce and Insurance. Chairs: Senators Gunn, Meredith, Wade

Senate Health Care: Chairs: Senators Hise, Krawiec, Pate.

Joint Legislative Oversight Commission on Health and Human Services. Chairs: Reps. Dobson, Lambeth. Senator Pate.