First, Do No Digital Harm:
Regulating Mobile Health Apps for the 21st Century

Statement for the Record

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Introduction. Chairman Burgess, Ranking Member Schakowsky, thank you for the opportunity to submit this testimony on the impact of mobile health apps on American Health Care. On a bipartisan basis, the Energy and Commerce Committee has taken the lead in ensuring the United States can take full advantage of innovation in mobile apps to improve cost, quality, and convenience in American health care. The 21st Century Cures Act, passed by the House in 2015 with overwhelming bipartisan support, is forward thinking. If passed into law, the policies it would implement would lead to a responsible and responsive regulatory environment for mobile health apps.

However, misguided policies could also derail the benefits of apps and other digital health technologies. Policies on payment and regulation, well intentioned proposals to move things along quicker, could have the unintended consequence of allowing these digital technologies to be swallowed by an unreformed health system that remains expensive, sluggish, and of uneven quality. The risk of Congress doing *too much* is at least as great as the risk of doing too little. The principal guiding Congress should be: *First, do no digital harm*. There are three areas in which Congressional action could have such unintended consequences: State licensing of physicians, interoperability of health data, and Medicare payment for telehealth.

State Licensing of Physicians. Historically, the practice of medicine has been regulated by the states. As telehealth has emerged, this has led some interested parties to conclude state licensing is (to some degree) obsolete. If technology permits a radiologist in Texas to read an image of a patient taken in any state, should that radiologist have to be licensed in every state? A short cut to solve this problem would appear to be to legislate a federal "safe harbor" for Medicare patients. This would comprise federal overreach that would be constitutionally suspect and unnecessary, because states are already solving this problem.

The American Telemedicine Association (ATA) produces a 50-state survey of telemedicine regulation. In its 2016 edition, it noted "twenty states averaged the highest composite grade suggesting a supportive policy landscape that accommodates telemedicine adoption and usage."[1] Although the trend is not uniformly positive, in an environment where it is not perfectly obvious what the appropriate regulation of the practice of telemedicine should always be, it is better to allow states to adopt, adapt, and improve appropriate regulations while learning from each other.

Further, the Federation of State Medical Boards has established an Interstate Medical Licensure Compact, which now has 17 states signed up, and legislation pending in nine more. This follows the Interstate Nurse Licensure Compact and the Physical Therapy Licensure Compact. This is another effective approach for achieving a national standard of licensure through professional collaboration, without federal overreach. Federal recognition of the compact is contained in Chairman Upton's *Patient Choice, Affordability, Responsibility, and Empowerment (CARE) Act*, and I urge the committee to allow the challenge of physician licensing to be resolved at the state level.

Interoperability of Health Data. Stimulated by $30 billion in funding via the HITECH Act in 2009, physicians and hospitals have gone on a rampage installing Electronic Health Records. One important goal of the so-called Meaningful Use program was that these records be interoperable, so that patient data could travel seamlessly across competing institutions in the

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[1]Thomas, LaToya, and Gary Capistrant, *State Telemedicine Gaps Analysis: Physician Practice Standards & Licensure*, American Telemedicine Association. January 2016, page 2.

health system. Everybody recognizes that interoperability has failed, and Congress has now gone a hunting for providers which deliberately block information from other providers.

This focus on interoperability through federal legislation and regulation has become an unhealthy obsession. The president's budget includes $5 million to support the development of interoperability standards and requirements. Following $30 ***billion***, another $5 ***million*** is unlikely to drag the federal mandate for interoperability across the finish line. No matter how compelling the public good appears, attempting to cajole competing health institutions into sharing their patients' health data is no more likely to succeed than trying to compel Boeing and Airbus to share the plans for their next super jumbo jet.

However, there are success stories *within* states. Take for example, an effort described by Dr. Toby Bloom, PhD, of the New York Genome Center. Under the auspices of one Institutional Review Board, six New York hospitals, and physician practices, have agreed to pool de-identified patient data for research purposes. The collaboration has the ability to remove duplicate records and hopes to merge genomic data into the database. It currently has data on five million patients and will eventually have ten million patients' records, according to Dr. Bloom.[2] That would amount to half the state's population – far in excess of the million patients whose digital health data President Obama wants to bio-bank for the Precision Medicine Initiative.[3]

If states were the locus of oversight for interoperability, researchers, patients and other interested parties might update the regulatory apparatus faster than waiting for Congress to act.

Medicare Payment for Telehealth. Historically, Congress has regarded telehealth as an opportunity for patients in rural areas to have better access to high quality specialized medicine. Medicare reimbursement for telehealth has been governed by this limited vision. In fact, telehealth is beneficial for patients in every environment. Medical care delivered remotely should be paid for, as is care delivered in person.

Unfortunately, the notion of "parity" which governs advocacy for telehealth reimbursement will not lead to cost reductions. There is little doubt telehealth can often be delivered at significantly lower cost than in-person visits. However, it is also the case that doctors' offices and other ambulatory facilities (such as surgery centers) deliver care at much lower cost than hospitals. This has been known for years, and President Obama has proposed "site neutral" Medicare payments that would save $29.5 billion over ten years.[4]

However, Congress has not been able to legislate this straightforward cost-saving measure. Similarly, if a patient can consult a physician effectively via an app on a mobile phone, but Medicare pays the physician the same as for an in-person visit, it is unlikely Medicare will save money. There is bipartisan agreement that Medicare should move away from paying fee-for-service and towards paying for value. Achieving this will require Medicare to give up its

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[2] Bloom, Toby, panel presentation, *Data-Driven Medicine in the Age of Genomics,* summit sponsored by the Health IT Now Coalition and the Center for Data Innovation of the Information Technology and Innovation Foundation held at the Reserve Officers Association, Washington, DC. December 11 2014.

[3] Obama, Barack, *Fact Sheet: Obama Administration Announces Key Actions to Accelerate Precision Medicine Initiative*, White House, February 25, 2016.

[4] Graham, John R., *Site Neutral Medicare Payments: A Good Idea from President Obama's Budget*, NCPA Health Policy Blog, February 13, 2015. Available at http://healthblog.ncpa.org/site-neutral-medicare-payments-a-good-idea-from-president-obamas-budget/.

futile efforts to determine fees for every single procedure a physician executes, whether in person or remotely. Instead, the rapid adoption of telehealth should be exploited for opportunities where taxpayers, patients, and providers are all rewarded for reducing costs.

Conclusion. U.S. health care is in dire need of disruption. The subcommittee's recognition that apps are a vehicle to provide this impetus is very welcome. Success will be determined as much by what Congress restrains from doing, as much as what it does. Thank you for the opportunity to submit comments.