

## Removing the Regulatory Barriers for Telemedicine

### Executive summary:

Telemedicine is a rapidly growing component of healthcare in the United States and people see its potential to fix many problems in the healthcare system. This policy analysis examines major regulatory barriers against adoption of telemedicine and defines the nature of the problem. Then it lists three policy options and examines their pros and cons. It finally recommends that HHS and FDA should take the leadership role to establish national standards and guidelines for the practice of telemedicine.

### Background:

Starting from the extension of hospital care to patients in remote areas, telemedicine has had a history of over forty years. The Institute of Medicine (IOM) defines telemedicine as “the use of electronic information and communications technologies to provide and support health care when distance separates the participants”<sup>1</sup>.

Telemedicine has a broad range of applications. The IOM workshop summary report<sup>2</sup> categorizes telemedicine by settings and predicts their promising trends. Home and community-based telemedicine includes telephone consultations that substitute office visits and home monitoring that permits remote data collection for disease management. One million Americans are using remote cardiac monitors and home monitoring is particularly promising for chronic disease management<sup>3</sup>. Another trend suggests adoption of devices that are smaller and closer to customers. The rise of mobile health is a good demonstration. There are more than 13,000 consumer health applications for the iPhone<sup>4</sup>. The second category is office-based telemedicine, utilizing “flat-screen, high-definition units with peripheral devices that can aid in physical examination of the patients”<sup>5</sup>. Store-and-forward technologies are widely used and teledermatology is a typical example. “More than five million Americans had their medical images read remotely” in 2012<sup>6</sup>. The last category is

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<sup>1</sup> Field, M.J.(1996).Telemedicine: A Guide to Assessing Telecommunications for Health Care. (1996). Retrieved from <http://www.nap.edu/catalog/5296.html>

<sup>2</sup> Lustig, T.A.(2012). The Role of Telehealth in an Evolving Health Care Environment. Retrieved from: [http://www.nap.edu/catalog.php?record\\_id=13466](http://www.nap.edu/catalog.php?record_id=13466)

<sup>3</sup> Telemedicine FAQs. Retrieved from <http://www.americantelemed.org/about-telemedicine/faqs#.U1jrMuZdXuk>

<sup>4</sup> Public Policy for Telehealth in 2013: It's Time for Government To Lead or Get Out of the Way - iHealthBeat. (2013, January 24). Retrieved from <http://www.ihealthbeat.org/perspectives/2013/public-policy-for-telehealth-in-2013-its-time-for-government-to-lead-or-get-out-of-the-way>

<sup>5</sup> Lustig, T.A.(2012). The Role of Telehealth in an Evolving Health Care Environment. Retrieved from: [http://www.nap.edu/catalog.php?record\\_id=13466](http://www.nap.edu/catalog.php?record_id=13466)

<sup>6</sup> American Telemedicine Association. Telemedicine FAQs. Retrieved from <http://www.americantelemed.org/about-telemedicine/faqs#.U1jrMuZdXuk>

hospital-based telemedicine. Over half of all U.S. hospitals now use some form of telemedicine. TeleICU and stroke care are two quickly growing areas. Telementoring and telerobotic surgery may also increase<sup>7</sup>.

Telemedicine is growing fast. According to a report from IMS Research, U.S. telemedicine revenue is predicted to grow from \$174.5 million in 2012 to \$707.9 million in 2017<sup>8</sup>. However, its adoption and utilization is still considered limited compared to expectation. About 10 million patients receive telemedicine services every year in the United States<sup>9</sup>. But early as in 1996, the IOM estimated “roughly 250 million patients and potential patients” users of telemedicine<sup>10</sup>. Evaluations of telemedicine programs in the U.S. suggest that none of them had fully exploited their technological capabilities<sup>11</sup>.

Expectations set the stage for judging the current conditions. Telemedicine is considered a promising solution to many problems in the U.S. healthcare system. Severe health professions workforce shortages are predicted to persist nationwide and exacerbated in rural areas in next decade<sup>12</sup>. Connecting healthcare practitioners in different places through telecommunication technologies could leverage workforce capacities and improve access to care. Huge and rising healthcare costs are a big concern and 75% of them due to chronic conditions<sup>13</sup>. The success of Veteran Health Administration (VHA)’s care management program that utilized home monitoring and remote support suggests possible paradigm shift in chronic disease management<sup>14</sup>. Under the Affordable Care Act, accessibility and affordability of quality healthcare are major goals. Accumulating evidence that supports better outcomes brought by telemedicine in cost effectiveness, quality and patient acceptance of care<sup>15</sup> shows its potential to help achieve these goals. Demand for

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<sup>7</sup> Lustig, T.A.(2012). The Role of Telehealth in an Evolving Health Care Environment. Retrieved from: [http://www.nap.edu/catalog.php?record\\_id=13466](http://www.nap.edu/catalog.php?record_id=13466)

<sup>8</sup> U.S. Telehealth Patients Growing Nearly Six-Fold by 201 - Today's Medical Developments. (2013, February 14). Retrieved from <http://www.onlinetmd.com/medical-manufacturing-design-telehealth-021413.aspx>

<sup>9</sup> Lustig, T.A.(2012). The Role of Telehealth in an Evolving Health Care Environment. Retrieved from: [http://www.nap.edu/catalog.php?record\\_id=13466](http://www.nap.edu/catalog.php?record_id=13466)

<sup>10</sup> Field, M.J.(1996).Telemedicine: A Guide to Assessing Telecommunications for Health Care. Retrieved from <http://www.nap.edu/catalog/5296.html>

<sup>11</sup> Bashshur, R., Shannon, G., & Sapci, H. (2005). Telemedicine evaluation. *Telemedicine Journal & e-Health*, 11(3), 296-316.

<sup>12</sup> Lustig, T.A.(2012). The Role of Telehealth in an Evolving Health Care Environment. Retrieved from: [http://www.nap.edu/catalog.php?record\\_id=13466](http://www.nap.edu/catalog.php?record_id=13466)

<sup>13</sup> Centers for Disease Control and Prevention. (2014). CDC-Chronic Disease Prevention and Health Promotion. Retrieved from <http://www.cdc.gov/fmo/topic/budget%20information/FY-2015-fact-sheets.html>

<sup>14</sup> Lustig, T.A.(2012). The Role of Telehealth in an Evolving Health Care Environment. Retrieved from: [http://www.nap.edu/catalog.php?record\\_id=13466](http://www.nap.edu/catalog.php?record_id=13466)

<sup>15</sup> American Telemedicine Association. (2013). Telemedicine’s Impact on Healthcare Cost and Quality. Retrieved from: <http://www.americantelemed.org/docs/default-source/policy/examples-of-research-outcomes---telemedicine's-impact-on-healthcare-cost-and-quality.pdf>

access to information for customers is becoming more tangible, and the development of portable mobile health is leading this direction.

There are regulatory barriers curbing the adoption of telemedicine. There is neither a national telemedicine policy nor a nationally adopted standard<sup>16</sup>. Under current state-based physician licensure system, licensing requirements and regulations on practice vary considerably across states<sup>17</sup>, which largely prevents interstate practice. The Health Care Safety Net Amendments Technical Correction Act of 2003 (H.R.3038) authorized grants to State professional licensing boards to reduce statutory and regulatory barriers to telemedicine<sup>18</sup>, but very few projects are active<sup>19</sup>. Insurance coverage for telemedicine also vary a lot: Medicare covers some telemedicine services simply under the same codes for on-site physician services, but coverage of others varies across plans; Medicaid plans have different coverage of telemedicine across states; Private insurance plans face less regulation about services they cover, so they have more flexibility and variation in telemedicine coverage<sup>20</sup>. Since most healthcare services involve third-party payment by insurance, those uncovered telemedicine services face disincentives for utilization by both providers and customers.

### **Problem:**

The core of the problem is the mismatch between current conditions and the ideal state of adoption and utilization of telemedicine. Despite the rapid growth and broad range of applications, telemedicine is expected to achieve even more.

There are multiple powers shaping the dynamic of this problem. Historically, telemedicine was expected to overcome geographical barriers and to improve access to quality healthcare in rural and remote areas<sup>21</sup>. Then new concerns appeared and people started to see the potential of telemedicine in addressing them. The relatively recent concerns in physician shortage, cost effectiveness, quality improvement and customer-orientation reflect changes in the healthcare system in

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<sup>16</sup> WHO. 2009 Global Survey on eHealth – USA profile. Retrieved from: <http://www.who.int/goe/publications/atlas/en/>

<sup>17</sup> Gilman, D. J. (2011). Physician licensure and telemedicine: some competitive issues raised by the prospect of practicing globally while regulating locally. *J. Health Care L. & Pol'y*, 14, 87.

<sup>18</sup> H.R.3038 - 108th Congress (2003-2004): Health Care Safety Net Amendments Technical Corrections Act of 2003. Retrieved from <http://beta.congress.gov/bill/108th-congress/house-bill/3038?q=%7B%22search%22%3A%5B%22telemedicine%22%5D%7D>

<sup>19</sup> HRSA. Telehealth. <http://www.hrsa.gov/ruralhealth/about/telehealth/telehealth.html>

<sup>20</sup> Telemedicine FAQs. Retrieved from <http://www.americantelemed.org/about-telemedicine/faqs#.U1jrMuZdXuk>

<sup>21</sup> Field, M.J.(1996).Telemedicine: A Guide to Assessing Telecommunications for Health Care. Retrieved from <http://www.nap.edu/catalog/5296.html>

the United States. Concurrent with new concerns, the advancement of health IT brings out new applications and possibility of telemedicine, such as telerobotic surgery and mobile health. On one hand, evolving concerns and technologies drive high the expectation of what could be achieved. On the other hand, the limited adoption and utilization suggest a power curbing the development of telemedicine in reality and many review studies list those barriers. Therefore, removing the barriers is a solution.

The importance of solving this problem lies in the projection of future as mentioned above. Rising costs, physician shortage, ambitious goals of Obamacare and more demand for customer's access to information indicate that the expectation of telemedicine will only increase and call for promoting the development of telemedicine.

Studies have touched on multiple factors that constraint the adoption and utilization of telemedicine, and regulatory barriers are a major one. Since the appeal of telemedicine largely comes from its capacity to break geographical separation, regulatory barriers that artificially limit its practice across states are curbing prospective competition. Variations in insurance coverage of telemedicine across states and across plans are preventing a more equitable distribution of the benefits from telemedicine.

### **Policy options to address the problem and criteria for selection:**

This paper presents three policy options to address some regulatory barriers in the field of telemedicine. Criteria for selection include impact, costs, and feasibility.

#### **1. Establishing national standards and guidelines for telemedicine**

This option would require the Department of Health and Human Services (HHS), to take the leadership role. It would establish the scope of telemedicine, evidence-based guidelines for practice, policy recommendation for states, and technological standards. While the option proposed here would keep guidelines and recommendations non-mandatory to respect state autonomy over regulating telemedicine and to reduce political resistance, it requires some mandatory minimum standards at a federal level for the practice of telemedicine and telemedicine technologies in terms of patient privacy protection.

Federal definition of telemedicine and evidence-based guidance would improve the awareness of the potential benefits of telemedicine among state policymakers and healthcare providers and disseminate innovations. The mandatory minimum standards are pivotal in assuring the quality of telemedicine and safety of patient privacy. Both impacts would further lead to better state policies for promoting

telemedicine and better adoption among healthcare providers. However, the impact on promoting adoption of telemedicine may take longer time to show due to longer causal chain. This regulation solution is relatively low in costs and quite feasible. An existing bill, the Telehealth Modernization Act of 2013 recently introduced in the House, proposed a non-mandatory definition of telemedicine and recommendations for states<sup>22</sup>, may suggest that this option is on the trend.

## **2.Improving licensure portability for telemedicine practice**

Since state-based licensure has long been there and no federal agency can compete with state boards in experience and expertise in regulating physician licensure, the establishment of a national licensure system is not feasible at current moment<sup>23</sup>. The option proposes permissions for interstate practice of telemedicine through Medicare and Medicaid. The Centers for Medicare & Medicaid Services (CMS) and the Federation of State Medical Boards (FSMB) would take the leadership role to establish special certification or licensure allowing interstate telemedicine services for Medicare and Medicaid beneficiaries.

The impact would be directly increase interstate practice of telemedicine and improve the access to telemedicine for Medicare and Medicaid beneficiaries. Other impacts could be better health outcomes among Medicare and Medicaid beneficiaries due to better access to telemedicine services and lower costs for the two programs. However, uncertainty about the implementation is a big concern. Adding new alternatives to a system that has already been complicated may increase the costs of licensing, which may impede interstate practice. The difficulty of negotiation reduces the feasibility of this option. But as Medicare and Medicaid receive federal funding and there is precedent of VHA in loosening the licensure restrictions, it is still feasible.

## **3. Increasing reimbursement in Medicaid and Medicare schemes**

This option directly provides financial incentives for Medicaid and Medicare providers to practice telemedicine. The CMS, the legitimated federal agency to establish healthcare coding and reimbursement levels, would be the leading actor. As ATA advocates for, policy change should lift current restrictions on telemedicine, including some patient location restrictions, communications technology restrictions, and coverage restrictions<sup>24</sup>. In a word, this option requires expanded

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<sup>22</sup> Feds Draft Legislation to Define "Telehealth"- Government Technology. (2014, January 9). Retrieved from <http://www.govtech.com/health/Feds-Draft-Legislation-to-Define-Telehealth-.html>

<sup>23</sup> Gilman, D. J. (2011). Physician licensure and telemedicine: some competitive issues raised by the prospect of practicing globally while regulating locally. *J. Health Care L. & Pol'y*, 14, 87.

<sup>24</sup>ATA asks Federal Government to Lift Restrictions on Telehealth for ACO's, Remote Monitoring – ATA (2014, March 5). Retrieved from <http://www.americantelemed.org/news-landing/2014/03/05/ata-asks-federal-government-to-lift-restrictions-on-telehealth-for-aco's-remote-monitoring#.U1kVCOZdXuk>

coverage of telemedicine and appropriate reimbursement that takes into account the added value of telemedicine.

Apparently, this policy change would increase adoption and utilization of telemedicine. But there are two difficulties. First, budget is always a battlefield. If the policy adds to federal budget, it would be harder to pass it. Second, although much evidence suggests telemedicine is more cost-effective than traditional care, it is difficult to come up with solid estimation of the real effect and decide a new list of telemedicine.

**Recommendation:** Establishing national standards and guidelines for telemedicine  
Establishing national standards and guidelines for telemedicine is likely to cost the least and implement the quickest among the three options. Although it may take longer time to show the impacts, it is a good starting point setting stage for harder and further steps. New standards and updated guidelines should be there to reflect the evolving role of telemedicine in healthcare systems. Since the three policy options are not excluding each other, this recommendation is trying to select for the current moment.

It is recommended that:

- The HSS lead the conversation to establish national standards and guidelines for telemedicine, collaborating with other government agencies such as VHA, and participants outside such as ATA. Actors inside the HSS include the Agency for Healthcare Research & Quality (AHRQ), the Office for the Advancement of Telehealth (OAT), and the Office of the National Coordinator for Health Information Technology (ONC);
- The HSS makes internal reorganization to expand the OAT<sup>25</sup>'s scope to reflect the evolving role of telemedicine in the healthcare system;
- The OAT releases the scope of telemedicine and policy recommendation for states;
- The ONC focuses on the establishment of technological standards and guidelines;
- AHRQ strengthens quality of research and evaluation on the cost-effectiveness and other impacts of telemedicine, and provides annual updates in guidelines for telemedicine practice that reflect new evidence and changes in practice.

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<sup>25</sup> the OAT is currently under rural health, HRSA.