August 29, 2013

Submitted Electronically

Dr. Farzad Mostashari, M.D., ScM
National Coordinator Office of the National Coordinator for Health Information Technology
Attention: FDASIA Report
Hubert H. Humphrey Building, Suite 729D
200 Independence Avenue, S.W.
U.S. Department of Health and Human Services
Washington, DC 20201


Dear Dr. Mostashari:

On behalf of our 84,000 member physical therapists, physical therapist assistants, and students of physical therapy, The American Physical Therapy Association (APTA) appreciates the opportunity to submit comments in response to the Food and Drug Administration Safety and Innovation Act (FDASIA) Request for Comments on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology, released on or around June 3, 2013.

APTA is committed to advancing the safety and quality of healthcare through health information technology (HIT) innovation and we are eager to work with the Office of the National Coordinator for Health Information Technology (ONC), the Food and Drug Administration (FDA) and the Federal Communications Commission (FCC) on health information technology’s evolving role in innovating health care delivery and impacting health care reform. APTA’s commitment includes, but is not limited to, the adoption of electronic health records (EHR) by its membership, implementation and enforcement of privacy and security protections, and utilization of electronic health information to support payment models such as accountable care organizations, emerging cost reducing e-care services such as tele-rehabilitation (tele-rehab)\(^1\), as well as fostering health information exchange, supporting coordinated patient-centered quality care through utilization of electronic health information, and being an active participant in the evolution of regulatory

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\(^1\) Physical therapists are not yet eligible for reimbursement for tele-rehabilitation services under federal insurance programs although physical therapists have been participants in tele-rehab research.
framework for HIT as it impacts patients and the physical therapists and physical therapist assistants in health care delivery.

APTA commends the ONC in its vision for and the development of a risk-based regulatory framework for health information technology (HIT) which encourages innovation yet keeps patient safety as a core objective. APTA would like to take this opportunity to comment on particular areas of importance to physical therapists.

We respectfully provide the following comments:

**HIT Risk and Innovation**

Issues relating to the lack of compatibility among operating systems, sustainability of hardware and software currently available and scalability of mobile platforms must be considered in assessing the risks of HIT and health information exchange (HIE). Many innovative mobile products have been developed yet lack interoperability or cannot be implemented on a large scale. Some products use open source software, copyrighted software or a combination of both which can impede expanded use of such technologies. Additionally, health data transmission platforms have security vulnerabilities which introduce privacy and security concerns for the patient. Since health information technology and information exchange is still in its infancy, the development of a regulatory framework in conjunction with a non-regulatory compliance framework for health technologies is essential. For the latter, collaboration and cooperation among the private market stakeholders, health care providers and government agencies must occur and continue as technologies evolve.

What is considered mHealth technology today may be vastly different in the years to come. Additionally, process and outcomes metrics in use cannot extend across the health care continuum until true interoperability has been achieved among health care providers. Therefore, fragmented information is provided from one provider to the next which could pose risks to patient safety as the recipient provider receives incomplete data on the patient’s condition or the patient’s condition has changed from what is transmitted as “real time” data (which oftentimes is not due to system interface and compatibility issues). The ECRI Institute’s top 10 HIT Hazard report for 2013\(^2\) listed patient/data mismatches in EHRs and other health IT systems and interoperability failures with medical devices and health IT systems as number 4 and 5. APTA supports the development of a regulatory framework for HIT and mHealth which provides adequate safeguards that protect the patient across their continuum of care while allowing for innovation.

**Regulatory Framework**

APTA supports an oversight framework for HIT, including mHealth, wireless health and e-care technologies, that reduces the risk of harm to the patient and invites clinician

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involvement by creating an environment in which the health care provider is encouraged to alert the appropriate authority or oversight body of a risk or incident without fear of regulatory repercussion.

APTA is aware of recent framework proposals by various organizations and agrees with a framework that encompasses the following:

1. The creation of standards, guidelines and best practices with the participation of all stakeholders, such as patients, clinicians, HIT developers and vendors, in which patient safety is at the forefront in the development and utilization of HIT. These standards, guidelines and best practices must allow for the evolution of technological changes and innovations.
2. Development of educational and training resources on these standards, guidelines and best practices for dissemination to stakeholders by industry, for example, providers, vendors and patients.
3. Development of a reporting system for potential and immediate adverse safety events and other HIT issues which allows for stakeholder participants to report without concerns that the reporter’s organization will be penalized (absent gross negligence or intent to harm). However, this reporting system must not create additional administrative burdens to the provider as they are currently dealing with multiple new reporting requirements.
4. Utilization of an existing regulatory entity (e.g., Patient Safety Organizations (PSOs)) to receive data on potential or immediate adverse safety events so that data can be analyzed and risks reduced. This information can be used to increase the quality of care provided to patients.

APTA emphasizes that a primary barrier to clinician and health care organization reporting is the administrative burden associated with it. Therefore, APTA agrees with the Bipartisan Policy Committee’s report that reporting should be embedded into HIT systems and work flows.³

Safety reporting must include an educational component for stakeholders on the federal protections that exist for patient safety reporting. Currently, barriers exist that potentially reduce clinician safety reporting. These include clinician’s lack of awareness of confidentiality protections that are provided under the Patient Safety Act, concern that a confidentiality provision of an existing agreement between a provider and institution or HIT vendor may be breached, or that institutional policies may be violated by reporting safety events. Individuals and entities that utilize HIT should be encouraged to identify, analyze and report safety events so that corrective action can be taken. Federal regulations – such as any related to accounting for disclosures involving HIT - should be drafted to promote safety event reporting and be non-punitive unless there is clear evidence of intentional disclosure or gross negligence.

To assure continued patient safety as technology advances, a committee should be formed that includes representatives from each stakeholder group to develop and revise as necessary standards, guidelines and best practices for investigating and analyzing HIT patient safety events. Recommendations should include guidelines that specify timely corrective action steps to reduce the risks associated with the safety event and mitigate patient harm.

**Health Care Settings**

Physical therapists play a critical role in a patient’s continuity of care as the patient transitions from one health care setting to another. Physical therapy services are provided in a variety of settings, including home care, hospitals, outpatient clinics or offices; inpatient rehabilitation facilities; skilled nursing, extended care, sub-acute facilities; Intermediate Care Facilities for People with Mental Retardation (ICF/MR); patients’ education or research centers, hospices and schools. Physical therapy efficiently aids a beneficiary in gaining the best possible function within the context of their medical condition. These services ensure the diagnosis of, interventions for, and prevention of impairments, functional limitations, and disabilities related to movement, function, and health. Often, physical therapy is an effective and less costly option than alternative treatments, such as surgery. Costs associated with hospital readmissions after surgical procedures can often be reduced by utilizing physical therapy.

Physical therapists are vital to ensuring patients attain an optimal level of mobility and safety in their environment and they are uniquely qualified to provide functional training and educate the patient and caregivers on important factors such as prevention of further injury, illness and/or decline in functional status and the resulting effects of immobility. In addition, physical therapists are able to recognize subtle changes in a person’s status that may require further evaluation or referral to other healthcare providers before the problems are exacerbated and require readmission. With this expertise, physical therapists are essential participants in health care integration. Their assessment and plan of care for the patient is critical to reducing complications, particularly in the LTPAC community and, therefore, it is important that information from each care team member at the varying settings is captured and exchanged based on the specialist’s area of expertise to optimize patient outcomes and reduce miscommunication among the varying providers.

Outpatient physical therapists and LTPAC settings receive patients from a variety of providers and care settings. Many originating providers have EHR systems which are not capable of health information exchange (HIE) with the recipient provider. APTA supports the development of HIT that is tailored to the unique needs of the patient in each care setting along the continuum of care as it is essential to determining medical necessity and delivering the highest quality of care. To accomplish this, regulatory framework pertaining to EHR systems and other clinical decision software should be flexible enough to allow for and encourage innovation. History demonstrates that clinical software is changing and advancing at a rapid pace. Industry data and certification standards can assist adoption of HIE among all providers – even those not eligible for federal incentive payments, however, those
standards and the regulations governing them must also be flexible enough to evolve with advances in technology. Most importantly, industry standards must consider economic feasibility and reduction of administrative burdens to providers.

Privacy Breach and Harm to Patient

Patient safety also includes ensuring that the appropriate privacy and security safeguards are incorporated in all HIT, including medical devices and mHealth apps, to protect patient privacy and confidentiality. A faulty medical device has the potential to physically harm a patient, while a breach of a patient’s protected health information could harm the patient emotionally and financially. APTA supports aligning and incorporating stringent privacy and security safeguards across federal agencies involved in health care delivery.

Mobile “Health and Fitness” Apps

The FDA has published Draft Guidance for Industry and Food and Drug Administration Staff – Mobile Medical Applications (issued 7/11/11). In this guidance, the FDA states that mobile applications (apps) such as the following are outside the medical device definition:

- Mobile apps that are solely used to log, record, track, evaluate, or make decisions or suggestions related to developing or maintaining general health and wellness, if not intended to cure, treat, diagnose, or mitigate a specific disease, disorder, patient state, or any specific, identifiable health condition.
- Mobile apps that are used as dietary tracking logs and appointment reminders, or provide dietary suggestions based on a calorie counter, posture suggestions, exercise suggestions, or similar decision tools that generally relate to a healthy lifestyle and wellness and are not intended to cure, mitigate, diagnose, or treat a disease or condition.

APTA is concerned that a mobile application that would not fall under FDA regulation as a medical device or associated medical device application, could potentially be harmful and patient harm could occur because there are few standards in place that provide the appropriate safety notice prior to a consumer utilizing a “fitness and wellness” app. Consider the following examples of incidents which could conceivably occur while an individual uses a “health and fitness” app:

1. An older adult downloads an app that is marketed to “increase your balance and strength.” One of the exercises is the single leg stance. The app instructs the user to complete 5 repetitions on each leg twice per day. When doing this exercise, the user is not instructed to stand next to a counter for support if needed. The individual does the single leg stance in the middle of the family room and when she performs the single leg stance on her left leg, she falls and hits her head against an end table.

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4 Similar to what happens in the unregulated dietary supplement market
2. An individual with post-operative hip replacement decides to download an app that includes hip exercises for strengthening. The individual wants to get stronger quickly and performs abduction and adduction exercises of the hip using Theraband and, in the process, dislocates the hip prosthesis.

3. A 65 year old individual who has been sedentary downloads an app because it “guarantees weight loss” by doing 4 simple exercises, 3 times per day to raise the user’s target heart rate to 220 beats per minute. While doing the exercises, the individual begins to have chest pain, shortness of breath, and becomes diaphoretic, creating a potential emergency situation.

4. An individual with low back pain downloads a fitness app of lower back exercises. After doing the exercises for one week, the pain in the user’s back increases and s/he begins to experience periods of incontinence. The user continues the exercises and thinks the pain is an indication that the exercises should be continued and increased. Had the user seen a physician advisory on the app prior to initiating the exercise program perhaps s/he would have seen a physician and a tumor in the sacral area of the spine would have been discovered.

Additionally, timely “recall” of such an app may not occur unless agency directives are coordinated and implemented. Although this request for information does not specify the Federal Trade Commission, directives should be considered collaboratively. For example, similar to the FTC’s “just in time” disclosures for developers related to consumer privacy notifications\(^5\), agency recommendations should be in place that

\[\text{http://www.ftc.gov/os/2013/02/130201mobileprivacyreport.pdf} \text{ (accessed August 27, 2013):}\]

- **Just-In-Time Disclosures.** The Report urges operating system providers to display just-in-time disclosures to consumers and obtain express, opt-in (rather than implied) consent before allowing apps to access sensitive information like geolocation (i.e., the real world physical location of a mobile device), and other information that consumers may find sensitive, such as contacts, photos, calendar entries or recorded audio or video. Thus, operating system providers and mobile app developers should carefully consider the types of personal information practices that require an opt-in rather than mere use of the app to evidence consent.

- **Privacy Dashboard.** The Report suggests that operating system providers should consider developing a privacy “dashboard” that would centralize privacy settings for various apps to allow consumers to easily review the types of information accessed by the apps they have downloaded. The “dashboard” model would enable consumers to determine which apps have access to different types of information about the consumer or the consumer’s device and to revisit the choices they initially made about the apps.

- **Icons.** The Report notes that operating system providers currently use status icons for a variety of purposes, such as indicating when an app is accessing geolocation information. The FTC suggests expansion of this practice to provide an icon that would indicate the transmission of personal information or other information more broadly.

- **Best Practices.** The Report recommends that operating system providers establish best practices for app developers. For example, operating system providers can compel app developers to make privacy disclosures to consumers by restricting access to their platforms.

- **Review of Apps.** The Report suggests that operating system providers should also make clear disclosures to consumers about the extent to which they review apps developed for their platforms. Such disclosures may include conditions for making apps available within the platform’s app marketplace and efforts to ensure continued compliance.

- **Do Not Track Mechanism.** The Report directs operating system providers to consider offering a “Do Not Track” (DNT) mechanism, which would provide consumers with the option to prevent tracking by advertising networks or
require an app developer to send a warning to a consumer who has downloaded its app if safety events related to health have occurred as a result of utilizing that fitness program, exercise, etc. Just as updates to application software are automatically sent to the consumer, adverse events or warnings could also be programmed by the app developer to automatically be sent to the user. Alternatively, a status icon could be used to alert a consumer to a safety event just as the FTC has suggested that a status icon be used to alert consumers that transmission of personal information is occurring. Perhaps best practices should also be in place to advise application distribution platforms (such as Google Play, App Store, etc.) to remove harmful apps from the market and alert downloaders of the app that has been shown to reach a designated threshold of consumer harm.

Additionally, adverse events could be reported by consumers to the FTC’s Consumer Protection Agency (CPA) which could create a repository to track these adverse safety events and list the number of events “potentially associated” with an app so that consumers could access the information on a centralized webpage to more effectively make a decision to download a particular app. The FTC could then prioritize investigations based on the number of adverse events that are being reported for a particular unregulated mobile app.

In regards to mHealth apps that are clearly within the FDA’s purview. APTA supports:

- Mobile-focused standards of operation and data protocols that are developed through stakeholder engagement which are streamlined and less complex, along with a governing certification body for mHealth apps and associated technologies.
- Private and public collaboration to expand and accelerate HIT innovation.
- Ongoing stakeholder collaboration with HIT governing bodies so that regulations among agencies are aligned, innovation is fostered, and providers are not prevented from caring for patients due to regulatory administrative and cost burdens.

other third parties as they use apps on their mobile devices. This approach allows consumers to make a single election, rather than case-by-case decisions for each app.

**App Developers:** Although some practices may be imposed upon app developers by operating system providers, as discussed above, app developers can take several steps to adopt the FTC’s recommendations, including:

- *Privacy Policies.* The FTC encourages all app developers to have a privacy policy, and to include reference to such policy when submitting apps to an operating system provider.
- *Just-In-Time Disclosures.* As with the recommendations for operating system providers, the Report suggests that app developers provide just-in-time disclosures and obtain affirmative express consent before collecting and sharing sensitive information.
- *Coordination with Advertising Networks.* The FTC argues for improved coordination and communication between app developers and advertising networks and other third parties that provide certain functions, such as data analytics, to ensure app developers have an adequate understanding of the software they are incorporating into their apps and can accurately describe such software to consumers.
- *Participation in Trade Associations.* The Report urges app developers to participate in trade associations and other industry organizations, particularly in the development of self-regulatory programs addressing privacy in mobile apps.
As HIT advances and wireless health technology expands nationwide, APTA remains concerned about those patients and providers who lack access to broadband coverage, particularly the elderly and low income and individuals in rural areas. The inadequacy of broadband coverage in certain geographic areas impedes not only access to care, but access to the latest technological advancements in high quality care. Accordingly, we encourage federal agency collaboration and alignment of regulations so that access to care is improved.

When broadband coverage is adequate, care access problems still may exist because many elderly and low income individuals do not have broadband access. APTA supports programs that provide free access to broadband for these populations so that they can more easily and immediately access necessary care. Additionally, APTA supports the expansion of reimbursement incentives for physical therapists, physical therapist assistants and other providers in providing tele-rehabilitation services. Physical therapists can effectively conduct telehealth consultations with appropriate patients/clients and caregivers. The following case is an example of how tele-rehab can reduce costs, increase access to necessary care, benefit and enhance the patient’s rehab experience:

Case Study – Remote Geographic Area in Alaska

Patient: 27-year-old male from Togiak, Alaska, experienced a bicycle/vehicle accident resulting in left lower extremity injuries:

- Grade II open tibia fracture
- Fracture of medial femoral condyle
- Anterior and posterior cruciate ligament tears
- Grade II to III medial collateral ligament tear
- Surgical intervention at Alaska Native Medical Center in Anchorage, AK

6 weeks post op: PT evaluation in Dillingham Regional Hospital

Intervention: 10 days of daily "hands on" therapeutic exercise, gait training, and functional training; ensure adherence with bracing and no weight bearing.

The patient was discharged to his home in Togiak to be followed up with weekly tele-rehabilitation physical therapy (PT) sessions. The tele-rehabilitation PT session was a 30-45 session via telemedicine Polycom system from Togiak to Dillingham, Alaska. During the sessions, the physical therapist and patient used interactive live video. The therapist had the patient perform exercises and gave instructions to the patient on therapeutic exercise modification and progress. The patient’s gait was observed and verbal cues were made to improve the patient’s gait pattern. As the sessions progressed, the patient’s home exercises were modified and advanced.
After 6 weeks of tele-rehabilitation, the patient had full weight-bearing capability, increased functional lower extremity strength and range of motion (ROM). The patient could ascend/descend stairs, walk on uneven terrain, and ride a bike.

The care team discussed the tele-rehab process and determined the following:

- Continuity of care was more manageable due to tele-rehabilitation.
- The patient’s continued rehabilitation was enhanced in the home environment due to family support.
- The expense of prolonged hospitalization was avoided.
- Follow-up appointment costs were avoided. In this case: Airfare, costs for food, housing and local transportation for follow-up.

In addition to barriers for the elderly, disabled, low income individuals, and individuals in remote and rural geographic areas, APTA considers the following barriers to a more broad adoption of wireless HIT across the country:

- Continued patient safety and privacy concerns due to interoperability issues among health care hardware and software systems
- Lack of funding opportunities or reimbursement incentives for the adoption of mHealth solutions, such as tele-rehab for physical therapists
- The absence of secure messaging capabilities between HIT systems
- Bandwidth constraints due to increased overall use, especially with data intensive medical device applications

**Conclusion**

In conclusion, it is vitally important that individuals, especially vulnerable populations such as children, the disabled, low income and at-risk adults, are able to access high quality care. The inability to obtain care or receive appropriate care results is a substantial cost to beneficiaries, states and the health care delivery system as a whole. Technological health innovation is reducing barriers to accessing care and studies have demonstrated the cost-reducing benefits of e-Care services. However, barriers with health data exchange which impact patient safety and privacy and security issues remain.

APTA commends the ONC for this request for comments on this complex issue. Successful HIT innovation and the vision of expansion to all health care providers will require increased and ongoing participation and collaboration with all stakeholders, both public and private. APTA looks forward to working with the ONC and related agencies in its efforts to ensure that HIT innovation continues with the appropriate intra-agency safeguards in place to prioritize patient safety and maximize patient health. Thank you for your consideration of our comments. If you have any questions, please contact Deborah Crandall, J.D., Senior Regulatory Affairs Specialist, at 703-706-3177 or deborahcrandall@apta.org.
Sincerely,

[Signature]

Paul Rockar, Jr. PT, DPT, MS
President

PR/dc