July 21, 2014

The Honorable Fred Upton, Chairman
U.S. House of Representatives
Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Upton:

On behalf of the 30 million men, women, and children affected by one of the nearly 7,000 known rare diseases, the National Organization for Rare Disorders (NORD) thanks Chairman Upton and the Energy & Commerce Committee for your continuing support of the rare disease community. We are excited to participate in the 21st Century Cures Initiative.

We welcome the opportunity to comment on the 21st Century Cures Initiative’s fourth white paper titled, “Leveraging Technology to Advance the Discovery, Development, and Delivery of Better Treatments and Cures.” This white paper requests feedback on how we can leverage existing and developing technologies to accelerate the pace of treatment discovery, development, and delivery.

To address these questions, we have developed the following proposals. We look forward to discussing these ideas with the Energy & Commerce Committee as the 21st Century Cures Initiative continues.

1. Assemble a Task Force on the Standardization of Health Data Collected Outside the Clinic

As the Energy and Commerce Committee recognizes in its white paper, new technological advances are allowing for the collection of patient data at an unprecedented rate. Data collected through wearables, mobile medical applications, health management applications, and other monitoring devices and consumer-focused digital health products are proving invaluable to healthcare professionals in treating patients. This is especially true for rare disease patients. The data collected could also prove valuable if placed in patient registries and natural history studies for research or drug development purposes.

This data may be wasted if it is not collected and stored in a standardized format, thus rendering the data impossible to analyze. Further, a patient’s data must be accessible to the patient and the patient’s healthcare providers, thus allowing it to be used in shared-decision making.
To facilitate the standardization and interoperability of patient-reported data, NORD recommends that Congress assemble a task force to study the perspectives and positions of consumer-focused health product innovators (such as application developers or consumer device makers), electronic health record developers, practicing physicians, experts in achieving interoperability, and related federal agencies. This task force should provide recommendations for the standardization of non-clinically sourced data.

2. Ensure the Privacy of Data within all Innovative Patient Data Collection Technology

With the advent of innovative patient data collection technology, the legal and regulatory framework must be updated to ensure patient privacy. The data collected by wearables, mobile medical and health management applications, and other consumer-focused products often includes individually identifiable health information.

To safeguard patient privacy, Congress must ensure these innovative collection technologies adhere to the same privacy standards that established health data collection technologies adhere to. This may require updating the current statutory language to reflect the rapid advancement in health data capturing technology.

3. Modernize the Reimbursement and Licensure Regulations for Telemedicine

Much like the collection of health data, the delivery of health care is rapidly changing due to technological innovation. One innovative delivery model that shows particular promise for the rare disease community is telemedicine. As a member of the Advisory Board of the Alliance for Connected Care, NORD recognizes the importance of being able to access one’s physician outside of the hospital or doctor’s office.

Telemedicine is especially important to the rare disease community, as many rare disease patients must travel far to see physicians who specialize in their disease or disease area. This distance is often prohibitive in accessing treatment, and can create insurance reimbursement issues as well. In addition, many patients with rare diseases have severe physical disabilities, thus making even a limited amount of travel difficult. Telemedicine allows rare disease patients to receive consultation from their physician in the comfort of their own home, thus greatly improving access to care and to the quality of life of the rare disease patient.

There are many regulatory hurdles physicians must overcome if they are to use telemedicine. First, physicians face steep reimbursement challenges when practicing telemedicine, especially within the Medicare and Medicaid programs, as telemedicine is often only reimbursed for beneficiaries who are living in very rural areas. Public and private health insurance models are also not adequately reimbursing for the physician’s consultative services, which makes up the vast majority of telemedicine services.
Second, there is a lack of a standard definition of telemedicine, thus creating different standards across health care practices and insurance plans. This exacerbates access and reimbursement issues, creating vast inequalities in accessing telemedicine across the nation.

Finally, in order to facilitate a greater use of telemedicine, the current medical licensure system must be reformed. Currently, State Medical Boards are responsible for setting licensing standards in each state, thus creating broad variation in application processes, fees, processing times, and requirements. Most states require a physician to be licensed within the state to practice telemedicine there. Thus, physicians who wish to practice telemedicine are required to obtain a medical license in each state where they have patients.

Together, these hurdles make practicing telemedicine extremely difficult, thus greatly limiting access to physicians who may not be geographically close to the rare disease patient. To overcome these hurdles, NORD requests that Congress address the current reimbursement and licensing regulations to facilitate a greater use of telemedicine. For example, Congress could lift geographic restrictions for practicing telemedicine under Medicare and Medicaid, and ensure reimbursement for telemedicine under the Medicare and Medicaid programs.

Thank you again for the opportunity to engage in this exciting and much-needed initiative. We look forward to working with Chairman Upton and the Energy & Commerce Committee as the 21st Century Cures Initiative continues, and we are grateful for the Chairman’s recognition of these extremely important issues within the rare disease community.

For questions regarding NORD or the above comments, please contact Diane Dorman, Vice President of Public Policy, at ddorman@rarediseases.org or (202) 588-5700 ext. 102.

Sincerely,

Peter L. Saltonstall
NORD President and CEO