AMERICAN SOCIETY OF PLASTIC SURGEONS®
THE PLASTIC SURGERY FOUNDATION™
444 East Algonquin Road • Arlington Heights, IL 60005-4664
847-228-9900 • www.plasticsurgery.org

21st Century Cures

Improving the pace and progress of medical innovation in the United States

Background

Medical innovation is happening at record speed, yet regulations in the United States are still stuck in the past. In particular, federal drug and device approvals are antiquated and do not reflect current business and research models. The lack of continuity between modern day innovation processes and government regulation must be updated in order to best serve our patients.

The Solution

It is time to update the way that medical care is discovered, developed and delivered in the United States. Improvements must be made to allow for clinical trials to be streamlined by removing the burdensome red tape currently in place. By removing this red tape, current regulatory challenges will be removed and the research and discovery process for clinical trials will be improved.

Interoperability between electronic health records is an essential part in ensuring that physicians can securely and efficiently access patient information no matter where the patient was previously treated. EHR vendors should have greater responsibility for delivering products that allow providers to meet the objectives of the meaningful use mandate, and they should bear full risk for any penalties that come in the event that interoperability is not achieved.

There are clear benefits for patients and providers in creating a new category of covered durable medical equipment, Substitute Disposable Medical Technology (SDMT). This new category will allow Medicare beneficiaries to access new, cutting edge technology in various settings, leading to flexibility in treatment options and a reduction in access disparity among Medicare patients. The current Medicare Durable Medical Equipment (DME) category is used primarily in hospital or facility settings, which inherently limits patient and provider options. The SMDT category will include technologies that can be used in an outpatient or home care setting for less cost. This is a natural, commonsense evolution of Medicare payment policy, and it will foster more appropriate, more patient-centered, and – through greater patient compliance – more effective care.

It is important that we provide seniors and individuals with disabilities with immediate access to new FDA-approved medical devices that are not currently covered by Medicare. This can be achieved by providing an option for medical device manufacturers to "opt-out" of the Medicare coverage determination process for at least three years. By opting out of this process, manufactures have time to obtain the necessary clinical evidence within the United States in order to support a stronger case for a future Medicare coverage decision. This change would reduce the obstacles Medicare beneficiaries currently face in trying to access these new technologies. It would also ensure that these patients are informed of the costs and allow them to self-pay before Medicare coverage is sought by the manufacturer. By allowing beneficiaries to have this option, clinical studies and data collection can take place and access to innovative technologies will be streamlined for patients in the United States.

The Physician Payments Sunshine Act ("Sunshine Act") was enacted with the intent of promoting transparency surrounding transfers of financial value between physicians and the medical device and pharmaceutical industries. The originally enacted legislative language and congressional intent bear this out, and organized medicine largely supported this objective. The Sunshine Act included twelve exclusions from reporting requirements, and among these were educational materials that directly benefit or are used by patients. These commonsense statutory exceptions were then misconstrued in the rulemaking process as CMS concluded that medical textbooks, peer-reviewed journals, journal reprints and journal supplements did not offer direct benefit to patients. It is imperative that we correct this mistake by clarifying that the aforementioned educational materials are exempt from reporting.

Congressional Request

Cosponsor and pass the *21st Century Cures Act* (H.R.6)
to improve the pace and process of medical innovation in the United States.