



MITA[®]
MEDICAL IMAGING
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BY ELECTRONIC DELIVERY

The Honorable Diana DeGette
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Upton

As the leading trade association representing the manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound therapeutic devices, the Medical Imaging & Technology Alliance (MITA) is writing to provide comments on the “21st Century Cures 2.0” discussion draft.

MITA supports modernizing public policy to support innovation and patient access to new technologies. Public policy that matches the current needs of the healthcare sector will promote public health, enable widespread and more facile patient access, and support adoption of innovative technologies. Medical imaging technologies play an essential role in the healthcare infrastructure and the care pathways of screening, evaluating, staging, managing, and effectively treating patients with cancer, heart disease, neurological disorders, and numerous other medical conditions.

Communication and Coverage of Breakthrough Technologies

MITA supports improved communication between the Food and Drug Administration (FDA) and Centers for Medicare & Medicaid Services (CMS) regarding breakthrough therapies. Such improved communication needs to include establishing expectations for how coverage of a product can be achieved thereby making the process more transparent, accountable and predictable for innovators seeking coverage. Communication also should include establishing expectations for such things as:

- Criteria for assessment
- Evaluation methods
- Timelines
- Appropriate endpoints
- Types of evidence to be considered

Progress has been made in accelerated regulatory approval of modern and innovative technologies through programs like the Breakthrough Devices Program. We urge a complementary priority review process for all other devices and procedures within the CMS for their coverage and reimbursement decisions. MITA supports inclusion of the Ensuring Patient Access to Critical Breakthrough Products Act to codify the Medicare Coverage of Innovative Technologies pathway at CMS. This is needed to address the gap between regulatory authorization and coding, coverage, and reimbursement that serves as a significant barrier to the adoption and utilization of innovative devices. But, we also see an opportunity for this legislation to direct CMS to develop a more transparent and collaborative process for working

with manufactureres and others regarding the expectation for evidence generation for Medicare coverage, in general.

Digital Health Technologies

We were encouraged to see continued interest in digital health technologies with the inclusion of a report about the use and validation of digital health technologies, including in patient-focused product development.

However, we believe more must be done to encourage CMS to implement policies that will ensure patient access to digital health technologies, including artificial intelligence. Several “software as a medical device” (SaMD) and “software in a medical device” (SiMD) products (usually grouped together under the heading of “artificial intelligence” [AI]) are either in development or are already available in various types of healthcare settings. These products—in alignment with the Quadruple Aim—promise to bring about (1) greater efficiency and effectiveness in the delivery of healthcare to improve population health, (2) enhancing patient experiences, (3) avoiding unnecessary costs and driving cost efficiency, and (4) improving the experiences of clinicians and healthcare staff.¹

Realizing the maximum potential of AI technologies will, however, require an alignment of policy incentives that appropriately reward early adoption and ongoing innovation. Existing coding, coverage, and payment mechanisms likely can be leveraged for AI, with some modification of the Medicare payment methodologies, as long as AI technologies are recognized as being novel and distinct from the products and services which have historically moved through these processes. Imaging procedures using AI technologies should be:

- Given distinct payment codes from existing diagnostic imaging services
- Covered as distinct imaging services and not only as an element of the underlying device
- Accounted for under the payment systems via such mechanisms as New Technology APCs, updated pass-through payment policies, direct costs for the calculation of practice expense relative value units (RVUs), physician work, including separate payment when acting as a separate and distinct service.

ARPA-H

MITA supports increased investment to drive development, application, and implementation of innovative healthcare products. Often, for medical technologies that offer treatment across multiple diseases and conditions, such as focused ultrasound or SaMD, the current research funding structure can be difficult to navigate. A truly independent agency focused on healthcare innovation might also be intersectional with and authoritative regarding existing federal entities involved in healthcare-related research and regulation.

Medical imaging technologies screen, diagnose, and guide the treatment of millions of Americans every year for everything from simple bone fractures to highly complicated cancers, cardiovascular disease and the complications from diabetes mellitus and long list of other illnesses and disorders. ARPA-H should focus its activities on the development of innovative diagnostic and therapeutic medical imaging and image-guided technologies that have the potential to impact the treatment of numerous diseases and conditions.

¹ <http://www.annfamned.org/content/12/6/573.full>

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We commend your commitment to build on the progress made in the 21st Century Cures Act by addressing changes needed to support patient access to innovative therapies and devices. We look forward to working with you to achieve these goals. If you have any questions, please contact Holly Grosholz, Senior Manager, Government Relations, at hgrosholz@medicalimaging.org or 703-841-3228.

Sincerely,

A handwritten signature in black ink, appearing to read "Patrick Hope". The signature is fluid and cursive, with a long horizontal stroke at the end.

Patrick Hope
Executive Director, MITA

MITA is the collective voice of manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound therapeutic devices. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging innovations. These products include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. MITA Member company technologies are an important part of our nation's healthcare infrastructure and are essential for the screening, diagnosis, staging, managing and effectively treating patients with cancer, heart disease, neurological degeneration, and numerous other medical conditions.