



July 31, 2024

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn Houe Office Building
Washington, DC 20515

The Honorable Larry Bucshon, MD
U.S. House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Bucshon:

On behalf of the more than 90,000 members of the American College of Surgeons (ACS), I appreciate the opportunity to respond to your request for information on the 21st Century Cures initiative and next steps. The ACS was founded more than a century ago as an organization dedicated to improving the quality of care for the surgical patient. We welcome the opportunity to build on the 21st Century Cures Act, which has done a great deal to promote high-quality care, reduce the regulatory burdens placed on physicians, streamline clinical workflows, and empower patients with data.

The Cures 2.0 Act, introduced in November 2021, includes many important priorities to further accelerate medical research and improve patient access to the highest quality health care. As Congress considers updating and reintroducing this legislation, it is important to note the ways that health care delivery and digital health technologies have evolved since 2021. Certain aspects of health care and federal programs have improved, such as expansion of digital health services beyond electronic health records, exploration of the potential of artificial intelligence (AI) to manage health care knowledge, and more. New health care business models also contribute to the changing landscape. As physician and practice focus continues to shift to value-based care, policy and technology must move to meet the needs of the various stakeholders—physicians, patients, caregivers, hospital systems, payers, etc. Given this transformation, we challenge Congress to use this exercise to understand the gaps of today, but also consider what should be the focus of lawmaking efforts in the future.

As we discuss below, we see opportunities to improve the nation's public health and emergency preparedness applying lessons learned from the COVID-19 pandemic, to strengthen interagency and public-private collaboration to improve regulation of AI and digital health technology, and to make breakthrough medical technology available to more patients. We urge Congress to carefully consider these issues as it further refines Cures 2.0 and identifies policy solutions that are essential for further progress.

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Public Health and Emergency Preparedness

The ACS appreciates that the Cures 2.0 legislation focused heavily on preparing for future pandemics and mass population events. Optimal patient care, particularly mass population care, requires more than a single service at a single moment; it requires an integrated system of acute care delivery, public health, and emergency management. As Congress and the Department of Health and Human Services (HHS) continue to develop a national strategy and infrastructure, we ask that policymakers consider the following:

- 1. Develop a National Trauma and Emergency Preparedness System built on a structure of Regional Medical Operation Centers that brings together emergency management, public health, and care coordination efforts*

A mass population event, such as a pandemic, challenges a health system's triage, casualty flow, and care, often highlighting the scarcity of resources. Our public health agencies, emergency management services, and acute-care health systems do not routinely work together, and there is no overarching body to assist in coordinating a prolonged emergency response. To address this challenge, the ACS envisions a National Trauma and Emergency Preparedness System (NTEPS) built on a network of Regional Medical Operation Centers (RMOCs) and applying practices from the nation's trauma systems. An NTEPS would strengthen local-regional coordination of casualty and resource distribution to enable effective acute care coordination as well as prolonged total health system mobilization when needed.

In addition to providing day-to-day trauma care, trauma systems form the backbone of disaster preparedness and response to other time-sensitive emergencies. This was clearly demonstrated during the COVID-19 pandemic. To address issues with coordination in real time during the pandemic, trauma surgeon leaders across the country established RMOCs to align and coordinate health systems, long-term care facilities, governments, and organizations for rapid response to the pandemic's demands.

An RMOC is a local/regional organization that manages casualty care in a surge event by integrating emergency management, public health, and acute medical care systems, with the goal of saving lives and enhancing rapid community recovery by balancing the distribution of resources and patients in the acute health care system.¹ In other words, RMOCs function as the "air traffic control" for coordination of the health and medical response in affected geographic areas across all health

¹ *Establishing Medical Operations Coordination Cells (MOCCs) for COVID-19*. Assistant Secretary for Preparedness and Response, April 24, 2020, files.asprtracie.hhs.gov/documents/aspr-tracie-mocc-webinar--4-24-20-final-slides.pdf.

care partners and along the continuum of care.² An RMOc may also function daily to coordinate ongoing community health care needs for patients with time-sensitive conditions or who may need to move between facilities, and can scale quickly from daily patient management to mass population management.

The RMOc structure was extremely successful in managing statewide responses during the early days of the COVID-19 pandemic. For example, the Western Washington Regional COVID Coordinating Center in Washington State contributed significantly to a lower COVID-19 fatality rate and more efficient use of resources compared to other states by providing: (1) early communication and coordination among stakeholders; (2) regional coordination of the casualty and resource distribution; (3) rapid access to viral testing for diagnosis, care, and surveillance; and (4) proactive management of long-term care, skilled nursing facility, and vulnerable populations.³ Likewise, in Texas, an RMOc under the South Texas Regional Advisory Council scaled up quickly in response to the February 2020 evacuation of COVID-19 exposed cruise ship passengers to Joint Base San Antonio-Lackland. The RMOc maintained the regional health care system for the non-COVID-19 sick and injured, coordinated COVID-19 casualty response with early load-balancing, organized personal protective equipment allocation and utilization guidelines, distributed Remdesivir, and anticipated issues through the Health System Stress Score.⁴

The models in Washington State and Texas are excellent examples of how the RMOc structure can be scaled quickly to address urgent need. Having a medical response organization like an RMOc that exists before surge events can make expansion more seamless when needed. Between surge events, RMOcs can facilitate the flow of patients with time-sensitive conditions in the acute health care system. By leveraging trauma systems, RMOcs can coordinate medical response across the spectrum of surge, from time-limited to protracted high resource events. RMOcs are also well-positioned to coordinate total population public health interventions like vaccination.

To meet the goal of building on the 21st Century Cures Act and establishing a national strategy for future pandemics, the ACS recommends that Congress encourage the development, implementation, and sustainment of RMOcs, as well as establish an overarching NTEPS that links local, state, and regional systems with a common data network and drives performance improvement,

² Stewart, Ronald M, et al. *How to Set Up a Regional Medical Operations Center to Manage the COVID-19 Pandemic*. American College of Surgeons, April 13, 2020, https://www.facs.org/media/h1ok1dkz/how_to_set_up_a_regional_medical_operations_center.pdf.

³ *A Coordinated COVID-19 Response Helped Western Washington State 'Flatten the Curve.'* American College of Surgeons, June 16, 2020, <https://www.sciencedaily.com/releases/2020/06/200616135756.htm>.

⁴ Petrie, Bonnie. *How San Antonio Is Preparing For The Possible Spread Of The Coronavirus*. Texas Standard, February 27, 2020, <https://www.texasstandard.org/stories/how-san-antonio-is-preparing-for-the-possible-spread-of-the-coronavirus/>.

readiness, and research. As a first step, Congress should pass language included in the Senate draft of the Pandemic All Hazards Preparedness reauthorization bill (S. 2333).

Section 103 of the legislation reauthorizes the Hospital Preparedness Program (HPP) and improves coordination and surge capacity of regional medical operations within and among health care coalitions. The language also requires eligible entities to establish and maintain or leverage existing capabilities to enable coordination of regional medical operations within a coalition and between multiple coalitions in close geographic proximity. This sets a framework for stronger coordination of regional response in an emergency by driving the HPP from solely planning for catastrophic events to having an active role in managing the day-to-day coordination for the care of patients, without needing to authorize additional funding.

2. Manage the population's ongoing acute care needs during public health emergencies

During the COVID-19 pandemic, many acute care services including elective surgeries and high-risk screenings were halted. While necessary at the time, in many cases, delaying services led to later disease detection, more advanced disease and other treatment complications in patients with acute conditions. For example, cancer screenings dropped 86% (colon) and 94% (breast and cervical) in 2020 compared to 2017-2019.⁵ Screening numbers have begun to rise but are 29% (breast), 36% (colon) and 35% (cervical) lower than pre-pandemic rates based on electronic health record data.⁶ This has led to drastic declines in cancer diagnosis, and the long-term impact has yet to be seen.

To reverse this trend, resume screening practices to pre-pandemic rates, and accommodate the ongoing backlog of patients, several measures must be considered. It will be necessary for surgical oncologists and others in the oncology community to collaborate with primary care physicians and health care systems, rethink organizational tactics, consider extended hours for increased access to screening services, and provide necessary resources, to name a few.

When considering strategies for future public health emergencies, Congress must keep in mind the need to manage ongoing acute care needs through at-home screening and other similar services. It is essential that we find ways to address acute condition prevention, early detection, and other related needs to

⁵ *Delayed Cancer Screenings*. EPIC Health Research Network, May 4, 2020, <https://ehrn.org/articles/delays-in-preventive-cancer-screenings-during-covid-19-pandemic/>.

⁶ *Delayed Cancer Screenings—A Second Look*. EPIC Health Research Network, July 17, 2020. <https://ehrn.org/articles/delayed-cancer-screenings-a-second-look/>.

ensure that the prevalence and severity of these conditions is not intensified during and after future public health emergencies as was the case during COVID-19.

3. Manage the blood pool and blood products

The COVID-19 pandemic resulted in an unprecedented shortage in the blood pool and low supply of blood products that persists today and has major implications across the health care system. As Congress determines priorities and strategies to support continued recovery from the pandemic and responses for the future, the ACS recommends that Congress highlight the blood pool as a critical element.

The national blood shortage can be attributed to many factors, including low rates of blood donations, a rise in the number of trauma cases and organ transplants, resumption of elective surgery, and advanced disease progression in patients who deferred care during the pandemic.⁷ **Therefore, the ACS urges Congress to prioritize solutions to the current national blood shortage and establish strategies to ensure the safety and availability of blood products. This should include investment to achieve evidence-based advances in robust screening and testing to limit the risk of infectious disease in the blood pool, as well as enhanced resources and infrastructure to help facilitate blood donation.**

4. Evaluating the health care business model post-pandemic

The COVID-19 pandemic demonstrated the need for Congress and HHS to evaluate the long-term financial stability of the health care sector. Nearly every facet of the industry faced significant financial hardship during the pandemic. While Congress and the administration took great strides to support the health care system at the time, more can be done now to ensure stability during future public health emergencies.

Commercial insurers have financial reserves funded from premium payments to cover extraordinary health care needs; however, little is known about the use of these emergency funds. Hospital reserves are limited and typically are used to cover new technologies and capital needs to meet accreditation standards. Finally, physicians have minimal ability to draw on cash reserves during a public health emergency. For these reasons, there must be an intensive review that examines the most rational and responsible way to create a sustainable workforce that allows the health care business model to function effectively now as well as respond if faced with future emergencies or pandemics. **We urge Congress and HHS to examine the current business model to better understand the state of the workforce,**

⁷ *Nation Confronts Severe Blood Shortage – Blood Donations Urgently Needed*. American Red Cross, June 14, 2021, <https://www.redcross.org/about-us/news-and-events/press-release/2021/nation-confronts-severe-blood-shortage-blood-donations-urgently-needed.html>.

funding needs, rural availability of care, access to care in underserved populations, and related issues.

Food and Drug Administration

We are entering an era of large language models and digital services that will stretch across every sector, including health care. The U.S. Food and Drug Administration (FDA) and other federal regulators have a critical role to play in the management and effective use of these innovative technologies. While ongoing regulatory and legislative policy development across federal agencies and in collaboration with stakeholders will surely be needed, the Cures 2.0 effort offers some important opportunities to support this next frontier of care delivery.

The ACS was pleased to see Cures 2.0 call for a report to Congress on efforts to ensure collaboration and alignment across the FDA. We agree that the points below are important topics for study, and we offer some additional considerations as the FDA works to advance and regulate digital health technologies.

- 1. Use of digital endpoints for regulatory review, including the validation and qualification of digital endpoints and digital biomarkers*

Endpoints are events or outcomes that can be measured objectively to determine whether an intervention being studied is beneficial. Biomarkers are objectively measured and evaluated indicators of normal processes or responses to a therapeutic intervention. These can include clinical tests such as measuring cholesterol levels, blood pressure, body temperature, or pulmonary function. Digital endpoints and biomarkers are consumer-generated physiological and behavioral assessments or measures collected through connected digital tools, i.e., digital versions of traditional endpoints and biomarkers. While traditional endpoints and biomarkers are required for FDA regulation, advanced digital tools allow for continuous, longitudinal, and more cost-effective data capture. Such data (digital biomarkers) can be used to supplement data captured by existing traditional biomarkers. **Digital endpoints and biomarkers must be validated appropriately before being used for regulatory review. Validation should include an assessment of the device that is used for data collection, which might include ensuring that the proper terminologies and data standards are used, and assessment of the biomarker itself. The proper stakeholders and experts, whether within the FDA, specialty societies, or others should be included in the validation process.**

- 2. Acceptance of decentralized trials*

Clinical trials are necessary to bring safe and effective drugs and devices to the market. However, many drugs and devices are developed on small populations in laboratory-controlled settings that may not be reflective of real-life experience with

a disease. Travel to study centers for traditional randomized controlled trials can be burdensome and further limit engagement. Decentralized clinical trials, on the other hand, are conducted in a study participant's home using digital tools. These can include more sensitive, objective measures with greater density of information (for example, samples can be taken multiple times a day, not just every few months), and can include many more study participants. **Although fully decentralized trials are not appropriate for all research, in many instances, decentralized trials can deeply enrich a study and the FDA should support the use of such trials.**

3. The use of digital health technologies in patient-focused development of products

Patient-focused products can enhance patient engagement and activation, facilitate shared decision-making and patient goal identification, enhance clinician/patient communication, and improve symptom monitoring, thereby supporting the overall goal of patient-centered care. Such products can include wearables, mobile medical apps, patient portals, and telehealth platforms. As new technologies advance, patient-facing products will play an increasing role in health care delivery, patient safety, and improved outcomes.

4. The use and validation of digital health technology tools

The ability to smoothly integrate digital health tools into a physician's workflow is central to the use of digital health tools. Digital health tools should reduce, not add to, a physician's cognitive burden. Digital health tools can enhance a physician's ability to gather, process, and exchange knowledge and ultimately improve patient care when the tool is developed using validated data sources and semantic data exchange standards in alignment with validated clinical workflows. This enables these tools to provide the right information at the right time and seamless incorporation into the clinical workflow. Validation of digital health tools is truly essential to physician trust, improving care delivery, and avoiding patient harm. There are many aspects to validation. Validation is necessary in terms of the technology/algorithm used, the patient population on which the device, especially in the case of AI, is trained, whether the outcomes are accurate and unbiased, and whether the tool is appropriate for the specific setting in which it is used. **Digital tools should not be validated by the FDA alone, but in collaboration with an appropriate specialty society, clinical expert, or physician informaticist to reinforce physician trust in the tool. Use and validation of digital health tools are two of the most critical areas for physicians to successfully realize the potential of these technologies.**

In addition to these areas of study, Cures 2.0 called for increasing the use of real-world evidence (RWE). RWE is the clinical evidence regarding the use and the potential benefits or risks of a medical product derived from analysis of real-world

data (RWD). RWD are data related to a patient's health status or delivery of care that can be collected from a variety of sources such as mobile devices, wearables, and sensors; patient generated data used in home-use settings; product and disease registries; claims and billing activities; electronic health records, and more. Such data can complement data that are collected through traditional means and enhance clinical decision-making.

Use of RWE is one way to leverage technology to harness vast amounts of data generated in the health care system. RWD and RWE can benefit physicians by providing a more complete picture of the patient's health status and response to therapies. RWD and RWE also have the potential to improve care delivery for diseases and conditions that progress quickly and for tracking the spread of disease.

For the FDA and other regulators, RWE is necessary for monitoring the safety of drugs and devices. Real world performance monitoring also plays a critical role in the regulation of devices trained in AI and machine learning (ML). As devices that use AI and ML evolve, RWD will be reported back to the FDA regarding the product's safety, effectiveness, and potential risks. The true power of AI and ML-based software lies in its ability to improve over time instead of remaining static. But this is problematic for regulation because the device that was approved or cleared may no longer be operating in a similar fashion as it learns. **RWD is necessary to show that the AI or ML-based device still functions appropriately and in the way that it was intended. RWD is also important for accurately training AI and ML algorithms. These data should be high quality, diverse, valid, and representative of the uses for which it will be applied.**

RWE and RWD would also be beneficial when developing guidelines of care. Today, care guidelines are developed through a retrospective review process and care guidelines cannot be easily adjusted in real-time to leverage new advances and technologies applied in medicine. With today's ability to gather data directly from patients and other clinical sources, RWD can be leveraged to better understand conditions, how they are treated with drugs and devices, and the effectiveness of these treatments throughout patients' care journey. Through continuous living assessments of knowledge, the guidelines could be adjusted for various factors, such as demographics, social determinants of health, completeness of therapy, compliance to therapy, etc., to better guide physicians as they care for patients.

This presents an opportunity for the FDA and the Centers for Disease Control and Prevention (CDC) to collaborate and develop a process that uses RWD to develop and then continually adjust clinical guidelines. This is especially important for high-risk conditions where medicine rapidly advances. Without the ability to update clinical guidelines for these conditions in real-time, essential best practices may be overlooked in the retrospective process used today. **We believe that the use of**

RWE could have a positive impact across many of the federal health care initiatives where the Centers for Medicare & Medicaid Services (CMS) and Office of the National Coordinator for Health Information Technology (ONC) could use the living guidelines created by specialty medicine in concert with the FDA and CDC to inform the development of quality and value-based incentive systems built around modern care processes and workflows.

It is critical that RWE based on RWD be validated before use by physicians or HHS. The data sources, methods of data collection, data quality, data completeness, whether the data are fit for purpose, and how the data are analyzed, must all be considered. There is a lack of standardized methodologies to develop RWE. Therefore, transparency is required for how the data are used and the effects of the use of RWE should be continuously examined for bias.

Centers for Medicare & Medicaid Services (CMS)

Cures 2.0 directs the Comptroller General of the United States to submit a report to Congress on recommendations for administrative actions that may be taken by the Secretary of HHS to enhance coverage and reimbursement approaches under the Medicare program for innovative technologies that increase access to health care, improve health care quality, decrease expenditures under the Medicare program, or otherwise improve the program or health care for beneficiaries under the Medicare program. Use of innovative technologies to support patient care will continue to expand and it is essential that Congress and HHS take steps to integrate these technologies into HHS programs to keep pace with the evolution and continual advancements in health care delivery. **The ACS encourages policymakers to also consider ways to better harmonize and integrate the operating structure of the Medicare program to improve interagency collaboration and communication.**

The ACS also urges Congress to direct CMS to consider additional facets of Medicare's process for determining coverage and payment rates. Most surgical devices are not billed separately; rather, reimbursement for their use is included in hospitals' diagnosis-related group (DRG) payments. **The ACS requests that CMS carefully assess how breakthrough device coverage would be included as part of additional Medicare payment models such as DRGs, ambulatory payment classifications, and per member per month payments, along with innovative payment models like bundled payments and alternative payment models, including when the devices are paid separately, such as through a new technology add-on payment.**

Additionally, understanding expenses incurred by health care facilities when adopting new technologies is an important aspect of Medicare coverage and

payment determination. **The ACS appreciates that Congress acknowledges the potential benefits of breakthrough devices, but we urge Congress to direct CMS, when determining payment, to consider additional costs for vendors, developers, health systems and more that may be passed on to clinicians when implementing these devices.**

The ACS is supportive of exploring coverage pathways for innovative technologies and believes that coverage of innovative technologies will only increase access to tools that can enhance care delivery, reduce inefficiencies, and improve value. Many of the innovative technologies on the market today do not fall under existing Medicare benefit categories. **As Congress directs HHS to explore new alternative coverage pathways, we recommend that HHS modernize the current Medicare benefit categories.**

Finally, modern health care delivery involves the use of clinical decision support, mobile apps, wearables, and technology based on AI, ML, and more. **We appreciate that Congress has taken steps to acknowledge the benefits of these technologies and recommend the creation of more distinct guidelines to define digital alternatives to treatment and therapies. The ACS believes that establishing a standardized process for coverage of these technologies will ultimately benefit patients, providers, and the broader health care industry.** For example, some devices that have already received FDA breakthrough designation utilize AI tools to enable faster and more accurate diagnosis and treatment recommendations for cancer and Alzheimer's patients.⁸ With clear pathways for coverage, the use of these innovative technologies will continue to expand and will increasingly be an essential part of modern care delivery.

Additional Considerations

Beyond the policy proposals presented in Cures 2.0, the ACS would like to offer some additional policy considerations as Congress develops further legislation.

- 1. Ensure the validity, reliability, and accuracy of AI and ML technology*

AI is the next frontier of health care innovation. This technology is already being implemented in health care settings across the country, and its use is only going to accelerate. Any legislative efforts in the digital health space must consider the critical role that AI does and will play.

AI-based tools present a tremendous opportunity to support physicians in organizing and managing knowledge to be applied for improved patient care and

⁸ Wolf, Mike. *Understanding the FDA's Breakthrough Device Program*. Med Device Online, July 8, 2019, <https://www.meddeviceonline.com/doc/understanding-the-fda-s-breakthrough-devices-program-0001>.

reductions in administrative burden and physicians' cognitive load. **But in order to realize the full potential of AI in health care, policymakers must ensure both physician and patient trust in AI technology. This will require a standardized regulatory framework developed in collaboration with stakeholders possessing clinical and technical expertise that guides the development and validation of algorithms.**

The data used to train algorithms is critical to their validity and reliability. **The data should be high quality, diverse, valid, and representative of the uses for which it will be applied, and there must be transparency in the source of the data, or knowledge base, that was used to develop, train, and test the algorithms.** The internet would be an example of a low quality, low trust knowledge base, while a clinical data registry, such as the ACS National Surgical Quality Improvement Program database would be a high quality, high trust knowledge base. When an AI-based tool is trained on a knowledge base with high rigor, it can be assumed that there is lower risk of error because the data used in development is high quality and trustworthy.

The nature of generative AI is to draw conclusions and produce content based on the data it is trained on and the question it is being asked. **Therefore, guardrails that guarantee the quality of the data input are critical to ensuring the accurate spread of information.** These include clear standards for data quality and reliability, verifying the credibility and expertise of sources used in AI algorithms, providing transparent documentation of data sources and methodologies, enabling independent validation and peer review of AI algorithms, and fostering a culture of transparency, openness, and accountability among stakeholders involved in AI development and deployment.

In addition, there must be transparency regarding when and how AI output is applied to patient care. This could come in the form of a “watermark” that confirms that an AI-based product or decision is in line with the highest clinical, quality, and regulatory standards. Groups like the ACS would be well-positioned to provide such validation for surgery. **There must also be transparency establishing clear lines of responsibility and liability for AI usage.** These guardrails should be established through a standardized regulatory framework in collaboration with clinical stakeholders.

Finally, it is critically important that there is a framework to ensure validity of the tool after implementation. AI-based tools and their outputs must be monitored over time to ensure validity as the tool learns and iterates. The ACS believes that clinical experts, such as physician informaticists, are best positioned to determine whether data used in AI applications are the best quality and the most appropriate from a clinical perspective, and to monitor the technology for clinical

validity as it evolves over time. The FDA should engage advisory groups for clinical and technical excellence that are condition or programmatically defined with cross specialty expertise, in order to ensure an AI tool is reliable and valid on multiple levels.

2. Update patient privacy and confidentiality regulations

As digital health continues to expand, privacy and security standards need to be updated to keep pace with modern technology and the innovative ways in which patients and providers access and interact with health data. Unfortunately, the ONC and CMS interoperability and patient access final rules do not go far enough in closing these ongoing gaps. For example, they rely simply on patient education and disclosure to protect patient privacy and place much of the onus on providers and payers to educate patients on how third-party applications could use their information. **Therefore, the ACS urges Congress to continue working with federal agencies such as ONC, the Office for Civil Rights, and the Office of the Inspector General to more broadly re-evaluate current enforcement mechanisms.**

In addition, we believe that patients should be in control of their own personal health information (PHI). **To achieve this, current regulations need to be updated to better ensure that data sharing will not occur unless a patient explicitly authorizes it and limit the extent to which third-party/direct-to-consumer applications and other non-HIPAA-covered entities can use and share patient data without the patient's knowledge and consent.** Updating privacy regulations is essential for establishing patient and clinician trust in new technologies. Establishing this trust will also reduce additional burdens on physicians related to determining which apps can be trusted when sharing PHI.

3. Conduct a thorough review of expanded telehealth services

Cures 2.0 requires HHS to issue guidance to states to clarify strategies to overcome existing barriers and increase access to telehealth under Medicaid and the Children's Health Insurance Program (CHIP). The ACS supports continued guidance from HHS to assist states in implementing telehealth programs. We also support the studies outlined in Cures 2.0, which address important components of telehealth access and utilization. **We encourage Congress to mandate such studies specifically examine the use of telehealth for the management of surgical patients, along with related barriers for telehealth integration in surgery.**

In addition, we encourage Congress to carefully consider which regulatory flexibilities implanted during the COVID-19 pandemic should be made permanent. **The ACS strongly supports revising the telehealth originating site requirement to allow individuals to access telehealth services from home, which has**

substantially increased access to telehealth services and reduced barriers to care for Medicare beneficiaries. However, proposals to permanently expand the types of practitioners who may furnish telehealth services and the services included on the telehealth services list should be carefully considered. **The ACS is concerned that the expansion of eligible practitioners may create significant scope of practice issues. This proposal may have unintended consequences for patient safety and appropriateness and could result in fraud and abuse of telehealth services under the Medicare program. In addition, the ACS recommends that CMS be required to conduct a thorough review of all services added to the telehealth services list during the pandemic to determine whether such services remain safe and appropriate to furnish via telehealth on a permanent basis.**

Concluding Remarks

The ACS is eager to build on advancements made by the 21st Century Cures Act in today's ever-changing health care environment. The lessons learned from the COVID-19 pandemic, the rapid development of AI-based health care technology, changing practice incentives, and more all create opportunities to strengthen our health care system. We urge Congress to consider the above proposals to improve the nation's public health and emergency preparedness infrastructure, strengthen interagency and public-private collaboration to improve regulation of AI and digital health technology, and take steps to make breakthrough medical technology available to more patients.

The ACS thanks Congress for its efforts to further refine Cures 2.0 and looks forward to working together on this and future legislation. For questions or additional information, please contact Emma Zimmerman with the ACS Division of Advocacy and Health Policy at ezimmerman@facs.org.

Sincerely,



Patricia L. Turner, MD, MBA, FACS
Executive Director & CEO