AMERICAN COLLEGE OF SURGEONS
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Highest Standards, Better Outcomes

100+years

March 19, 2020

Donald Rucker, M.D.
National Coordinator for Health Information Technology
Department of Health and Human Services
330 C Street NW Washington, DC 20201

Re: 2020-2025 Federal Health IT Strategic Plan

Dear Dr. Rucker:

On behalf of the over 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Office of the National Coordinator for Health Information Technology (ONC) 2020-2025 Federal Health IT Strategic Plan. The ACS is a scientific and educational association of surgeons, founded in 1913, to improve the quality of care for the surgical patient by setting high standards for surgical education and practice.

The College supports the overarching goals that ONC identified in the 2020-2025 Federal Health IT Strategic Plan, as well as the roadmap to achieve these goals. The ONC continues to keep the patient at the forefront throughout the goals and objectives, and the College agrees this is vital. At the same time, the role of privacy and security are of the highest importance, especially as technology allows patients to have increased access to their health data on demand. Technology solutions must assure patient data remains secure while simultaneously meeting the challenge of leveraging those data for better healthcare at a lower cost. The College agrees that the advanced use of health IT can increase value of healthcare while reducing costs, as well as further the role of the patient in care management.

The ONC highlights the principles that were at the center of the development of this plan, including, as discussed above, putting the individual first: "embrace person-centered care that values the whole individual, including their goals, values, culture, and privacy." The College sees this as an opportunity to ensure that *value* is defined and informed by what is most important to the patient. Value should inherently be defined and determined by the patient, including their goals based on their conditions, diagnoses, and social factors. Digital health tools create the opportunity for patients to share and report data and progress towards their goals using third-party applications. Similar tools could also be used to make data accessible to patients on physicians regarding value, allowing patients to be better informed when making decisions about their care. Further, this is another opportunity to prioritize technology solutions that better integrate social factors into health data, creating a more complete picture of health, and allowing clinicians to better design care models most appropriate to the patient. The College offers overarching recommendations in the *Opportunities* section of this document, and then responds with feedback and further recommendations where they fit within the specific goals and objectives.

Challenges in Healthcare

The challenges in healthcare continue to grow in complexity, and as the ONC described, it is the responsibility of the government and the industry at large to ensure that technology does not exacerbate these challenges. Health IT should be used to expand care access, work toward the elimination of health disparities, address public health crises, and improve health outcomes. This requires a careful balance between encouraging innovation, allowing patient choice and data ownership, and ensuring appropriate privacy protections. Detailed below are the College's suggestions to better achieve this balance within the goals and objectives outlined in the Strategic Plan.

Opportunities in a digital health system

The ACS agrees with the ONC that health IT gives patients the tools to become active participants in their care. By providing patients with data, they become better informed about their options, and can also manage their care to their own goals, allowing clinicians to create individualized care plans and track outcomes according to stated patient goals. Using digital health tools, including certified third-party applications, can be an option through which patients can access health information, communicate with their care team, and comprehend their health and treatment options in easily understood terms, including videos and step-by-step guides to prepare for procedures. Access to health data through various safe mediums, done so with health literacy in mind, can empower patients to manage and improve their health. Incorporating patient reported outcomes (PROs) into existing reporting programs will shift the system towards value as defined by the patient, rather than by the payer. This, alongside many of the health IT advances discussed below, will help put the patient at the center of their care, and provide meaningful data to clinicians to reduce administrative burden and improve quality of care.

The ONC states: "strategies to advance health IT should minimize burden by considering how best to incorporate technologies into existing workflows and reducing reporting requirements." The ACS agrees with this strategic direction and supports a system-wide shift toward a focus on clinical care models, rather than reimbursement models. We support a system grounded in an open-source architecture using standard knowledge artifacts (discrete data points or clinical information within a workflow) that allows for data to move to various repositories, such as EHRs and registries using national standards. The ACS sees the digital health system as an opportunity to move the landscape systematically beyond an EHR-centric system to a system designed around a patient that is approachable, understandable, and usable. To achieve this, the focus should shift to the use of data digital services to track and inform patient-conditions or episodes of care, rather than relying on systems which were built for purposes of payment and reimbursement.

Specifically, ACS recommends that HHS agencies and offices work to:

1. Further enhance interoperability through a vendor-agnostic, open-source patient cloud;

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2. Provide governance to a knowledge repository containing knowledge artifacts (standard workflows and semantic standards);

3. Develop a process with other HHS agencies for digital services certification, including clinical and technical verification, of new products (including wearables, third-party applications, and Artificial Intelligence (AI)/Machine Learning (ML));

4. Update privacy regulations to better align with advanced technology;

5. Create a Universal Patient Identifier (UPI).

Details on these strategic recommendations are described below.

1. *Further enhance interoperability through a vendor-agnostic, open-source patient cloud*

The ACS' long-term vision of a patient-centric care model supported by team-based care, rooted in a culture of continuous quality improvement, can be achieved through advanced digital technology and a standard data infrastructure. **Federal support of a vendor-agnostic, open-source patient cloud architecture would shift the industry to a patient-centric system that eases the current burdens with interoperability**. The patient cloud aggregates data through a **common data model** to create a single, unique, and more complete patient medical record. This can provide physicians with the information they need to deliver the highest quality care while keeping costs low and give patients agency over their own data. Grounded in standards for data exchange from the 21st Century Cures Act, a patient cloud could bi-directionally exchange health data through Application Programming Interfaces (APIs) using Fast Healthcare Interoperability Resources (FHIR) between any system, including EHRs, third-party applications, registries, and wearable devices. Federal support of a patient cloud will further advance interoperability, allow for the use of more advanced technologies, and empower the patient and clinician with more accurate, current, and complete data. It is conceivable that multiple vendors could implement a common architecture and share across platforms. Individual commercial platforms which conform to a standard common data model can also add their own services as an overlay to meet the various needs in their markets. Without this open-source cloud platform and common data model, the industry will remain siloed, limited by costly proprietary solutions to data exchange and aggregation.

2. *Provide governance to a knowledge repository containing knowledge artifacts (standard workflows and semantic standards)*

As a step toward achieving data consistency and standardization within the cloud, ACS recommends the creation of a knowledge repository, containing clinical care models in open standards notation and key knowledge artifacts, housed in the National Library of Medicine (NLM), and governed at the Federal level with a public private partnership, similar to the National Interoperability Collaborative (NIC) in the United

Kingdom.[1] These care models and knowledge artifacts housed within the knowledge repository would include standard workflows for clinical conditions, including the discrete data points commonly documented throughout the process. By creating semantic standards for data collection and clinical workflows, structured, discrete data would enable the capture of high-fidelity data across organizations and systems, increasing interoperability and expanding digital health beyond EHR-centric models. The ONC should work with specialty societies and agencies to develop a governance structure for the knowledge repository and to provide oversight to ongoing maintenance and updates to semantic standards and workflows to ensure they remain current with clinical practice guidelines. Organizations such as the ACS would provide practice guidelines which highlight critical nodes in a care process for patients and surgeons to consider. Governance of the model could be constructed similarly to the DaVinci project, where specialty societies and physician informaticists inform the standards to be implemented, review the clinical guidelines, and agencies provide oversight to manage long-term maintenance and ensure sustainability and scalability.

With standardized care models and knowledge artifacts, technology solutions could be laid on top of workflows, creating digital representations through computer-readable code, providing clinicians with access to the most current clinical best practices within their source system(s). A vendor-agnostic data model will encourage innovation, minimize free-text workflows, and avoid proprietary models from developing, as well as create consistency across systems and clinicians that will enhance data reliability and validity. This would allow for living notations of knowledge artifacts and would move away from an EHR-centric system, to one designed to ensure patients receive high-quality care based in the most current clinical practice, facilitated by advanced technology solutions and an open-source patient cloud.

It is important to realize the ACS framework focuses on curating surgical healthcare knowledge using standards and structured data capture in a platform separate and distinct from the EHRs. This way, the knowledge artifacts are available for sharing with EHRs, registries, and with other stakeholders. This represents a change in data flows. These data are captured using structured, standardized fields, layered on top of the EHR for seamless workflow integration, and then aggregated and normalized within a cloud. These data can then be delivered to other digital platforms using FHIR. If we proceed as EHRs had initially hoped for, without standard knowledge artifacts, then clinical workflows and data capture will remain mired in proprietary systems and vendor specificity, increasing the burden to exchange data, and making benchmarking across cohorts lack rigor and meaningful comparison.

3. *Advanced digital health technologies: Developing a process for technology certification*

ACS believes the shift to cloud environments with the use of standard, accessible knowledge artifacts to design shared workflows will better enable an ecosystem that can make the most of advanced technologies, including AI/ML and the Internet of

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[1] National Interoperability Collaborative. https://nic-us.org/. Accessed March 18, 2020.

Things (IoT). However, what is needed to make this successful is a certification process for advanced technologies and software to ensure the safety and efficacy of new solutions—including AI/ML. The ONC should work with other agencies, such as the FDA, to develop a certification process to assure a common method for all to follow. The certification should confirm that the digital service has appropriate clinical logic, valid technology and standards, and has met privacy requirements. Without a certification process, patients and clinicians will be left on their own to verify if a source or product is trusted. The current openness of the third-party application market puts patient safety at risk and will create further administrative burden for clinicians.

The opportunities to leverage digital health technologies are endless and have the potential to transform care. One of these opportunities is for technology to assist clinicians in processing and distilling mass amounts of ever-increasing clinical knowledge and evidence-informed treatment options. AI/ML and forms of Clinical Decision Support (CDS) provide a technological option that can store, process, and review mass amounts of data from multiple sources and guide providers through treatment options based on individualized patient needs.[2] These types of technology could reduce documentation burden for physicians, and re-design patient care to be *driven* by the individual patient and their needs, rather than those of the payer(s). These technologies could be developed and designed using the standard knowledge artifacts described above, furthering consistency and standardization across clinicians.

An example of a possible certification process is detailed below:

- ONC, in partnership with medical and surgical professional societies and physician and technical expert panels, create a technology certification process for technologies that fall outside of FDA guidance and ONC CEHRT (similar to the Trusted Exchange Framework and Common Agreement (TEFCA) and the Sequoia project);
- Specialty societies or physician panels review the products for clinical accuracy and appropriate use of the knowledge artifacts;
- All products attest to certain minimum privacy and security requirements.

4. *Update privacy regulations to better align with advanced technology*

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 physicians access and interact with health data. **ACS urges ONC to continue working with Congress and other federal agencies such as the Office for Civil Rights (OCR) and the Office of the Inspector General (OIG) to more broadly re-evaluate current policies and enforcement mechanisms**. Current regulations need to be updated to better ensure that data sharing will not occur unless a patient explicitly authorizes it and

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org

Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: djohnson@facs.org

facs.org

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[2]Weiner, M., & Biondich, P. 2006. The influence of information technology on patient-physician relationships. Journal of general internal medicine, 2 (1):S35–S39. doi:10.1111/j.1525-1497.2006.00307.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1484834/. Accessed on March 19, 2020.

limit the extent to which third-party/direct-to-consumer applications and other non–HIPAA-covered entities can use and share patient data. Further, the ONC should work with the private sector to ensure patients are well-informed and educated about sharing their health data with entities not currently governed by HIPAA. It is vital that patients understand who will have their data, for how long, what it can be used for, if it can be sold, and more.

5. *Create a Universal Patient Identifier (UPI)*

Congress's initial intent for patient privacy and data security developed when digital information was locked into a single EHR and the Congress thought of care as a single point of contact between a patient and a clinician. We now know an individual patient is treated across a care continuum by several clinicians and data sharing are essential to coordinate, optimize care, and reduce costs. Current law keeps information locked away and makes true data sharing for optimal care problematic, but private and secure. The ACS believes patients should have the option to better enhance their care between clinicians by advancing, in a secure and private manner, a universal patient identifier (UPI). Without a UPI, the industry is forced to use work-around methods to match patient data. Inaccurate patient matching can lead to adverse events, compromised safety and privacy, inappropriate and unnecessary care, unnecessary burden on both patients and physicians to correct misidentifications, time consuming and expensive burden on health systems to detect and reconcile duplicate patient records and improper record merges, increased health care costs, and poor oversight of fraud and abuse. Inaccurate data matching also poses a significant risk to patient safety because information may be unavailable when needed or records may be merged incorrectly, leading to inappropriate and even unsafe care.

Errors in individual data matching will be compounded with the expansion of electronic health information sharing. Further, in the absence of a UPI, algorithms are left to rely on other personal data, including, but not limited to, social security number, birthdate, address, and credit information. **ACS continues to support legislative efforts to allow HHS to explore and adopt a UPI as it would help to ensure that surgeons have a safer, more accurate and consistent way of linking patients to their health information across the continuum of care.**

In the absence of a legislative fix for this issue, the ACS recommends that ONC continue to explore alternative solutions. A standard algorithm hosted in a cloud platform that assesses and determines patient matches based on identifying information, such as name, date of birth, Payer ID, or other unique identifiers, could be a stop-gap solution. Further, standard requirements for patient identifiers as part of the USCDI, such as number of digits and inclusion of hyphens, dashes, and apostrophes, as well as consistency in other demographic data fields, could aid with this issue by standardizing demographic information in EHRs and apps. However, these options will not solve this problem completely, and ACS advocates for a larger legislative fix for this issue, as it will only grow in size as digital technology continues to increase in scope and practice.

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: djohnson@facs.org
facs.org

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Goals, Objectives, and Strategies

The Federal Health IT Strategic Plan 2020-2025 has four goals, each with a series of objectives, for how the federal government can create a modern health IT-enabled system. The goals are grounded with consideration for the above opportunities, and are broad in order to cover the scope of HIT applications across the federal government.

Goal 1: Promote Health and Wellness

The first goal stated in the strategic plan is to **"promote health and wellness."** The objectives outlined to meet this goal are: improve individual access to health information; advance healthy and safe practices through health IT; and to integrate health and human services information.

Objective 1a: Improve individual access to health information

The ACS agrees that digital health tools can better empower patients to be engaged in their care and own their health data. As the ONC described, it is important that these digital tools are accessible, safe, and at the appropriate health literacy level in order to best empower patients and personalize care management. The ACS believes that it is important that digital tools make health data consumable, understandable, and do so in a safe way.

From a perspective of condition-specific care management, ACS believes that digital tools, when used correctly and containing appropriate and relevant clinical health information, can create helpful dialogue between patients and their care team to manage their disease and have questions answered in real-time. To advance health and wellbeing, the many knowledge artifacts that we have for conditions and care management can be used within applications and tools that cater to the specific needs of individual patients.

Objective 1b: Advance healthy and safe practices through health IT

One of the many positives that come from the use of patient-facing tools and wearables is the ability for patients to set and share progress toward personal care goals with their care team. The ACS believes that the most beneficial form of patient-generated health data (PGHD) are in the form of PROs. The integration of the patient experiences and milestones within the clinician workflow, including the collection of PROs in more frequent, but brief, occurrences throughout their episode of care, can provide meaningful information to physicians about progress on care goals, post-surgical recovery, pain management, rehab, and therapy. Patient portals and third-party applications connected to EHRs through APIs could create additional options for PROs to become a part of clinical decision making and create a simple interface for users to respond to questions and share data with their physicians.

Objective 1c: Integrate health and human services information

The College supports ONC's strategy of incorporating social determinants of health data at both the individual and population levels in order to better provide individualized, person-centered care. Using health IT to standardize the capture of these data, and to allow for bi-directional exchange across platforms and sectors, will create a more integrated, cohesive data environment, and a more comprehensive picture of whole-person health. ACS believes in the importance of accounting for social risk factors both within developing care plans and for evaluating quality.

However, most of the research and analysis conducted to date focuses on using information found in Medicare administrative claims data, which has limited information on social factors. More broadly, much of the data used in quality evaluation and in medical research often lack diversity. The majority of individualized data in medical research are from white, middle-aged men, and the National Institute of Health (NIH) has had a long-term goal of increasing the diversity of research data.[3] The NIH has created the Precision Medicine Initiative, also known as the *All of Us* research project, to combat this history and reach out to minority and under-represented communities in order to increase the diversity of medical data available to researchers.[4]

In order to improve the diversity of data sets and to ensure these data include relevant social factors to provide a more comprehensive view of whole-person health across diverse patients and populations, the ACS encourages the ONC to work with standards-setting bodies, such as HL7, to include standardized elements for collecting social determinants data. These elements should then be included as part of FHIR, USCDI, and other relevant data sets and standards. Consistency in the documentation of social elements will allow for integration and assessment within care planning and quality measurement, allow for increased accuracy when adjusting for risk, and ensure that care is individualized to the patient's specific needs. The enrichment of data with these added factors and across a more diverse population will also contribute to advancements in the generalizability of data. Standards also allow for the use of tools and technologies that will be able to aid clinicians in providing referrals for patients to community resources that meet their social needs.

Goal 2: Enhance the Delivery and Experience of Care

The second goal within the strategic plan is to **enhance the delivery and experience of care.** The objectives outlined are: to ensure safe and high-quality care through the use of health IT; foster competition, transparency, and affordability in healthcare;

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[3] Oh, S. S., Galanter, J., Thakur, N., Pino-Yanes, M., Barcelo, N. E., White, M. J., Burchard, E. G. 2015. Diversity in Clinical and Biomedical Research: A Promise Yet to Be Fulfilled. *PLoS medicine*. *12*(12). e1001918. doi:10.1371/journal.pmed.1001918. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4679830/. Accessed March 19, 2020.
[4] National Institute of Health. *All of Us Research Program.* https://allofus.nih.gov/. Accessed March 18, 2020.

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: djohnson@facs.org
facs.org

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reduce regulatory and administrative burden on physicians; and enable efficient management of resources and a workforce confidently using health IT.

The ONC states that the system today is driven by payer preferences, rather than by consumer choice. The ONC believes that health IT can help move the system away from this through providing the information patients need to make informed choices about their care and treatment options in real-time. The College agrees that giving patients upfront information on their care options, including cost data, will help move the system towards being consumer, rather than payer, focused. The College further believes that the system needs to shift away from models that are based in the needs of payers and their required documentation and move to **care models** that are based on condition and clinical specific needs of patients across the continuum of care.

Care has advanced from a "cottage industry," where it was once provided in a single setting, to an incredibly complex model with many different levels, entities, and system. These modern care models require supporting elements such as proper resources, data to inform the care team, supporting revenue models and aligned incentive models. The knowledge involved is complex; for example, it consists of individual clinical findings, imaging reports, pathology, laboratory, treatment goals and patient reports about their experiences. Adding to the complexity, the U.S. health system continues to struggle to transition from a fee-for-service framework from the cottage industry days to a more complex model for modern care. ONC can play a pivotal role in supporting the knowledge management which is essential to the team providing care today and also critical in the shift from fee-for-service. In current day, care models have evolved to be team-based with primary care physicians (PCPs) coordinating with patients and a broad array of specialty medicine, including surgeons. In order to support a patient appropriately throughout the continuum of care for their condition, the care team requires shared knowledge from a **common data model**, as illustrated in the figure below.

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
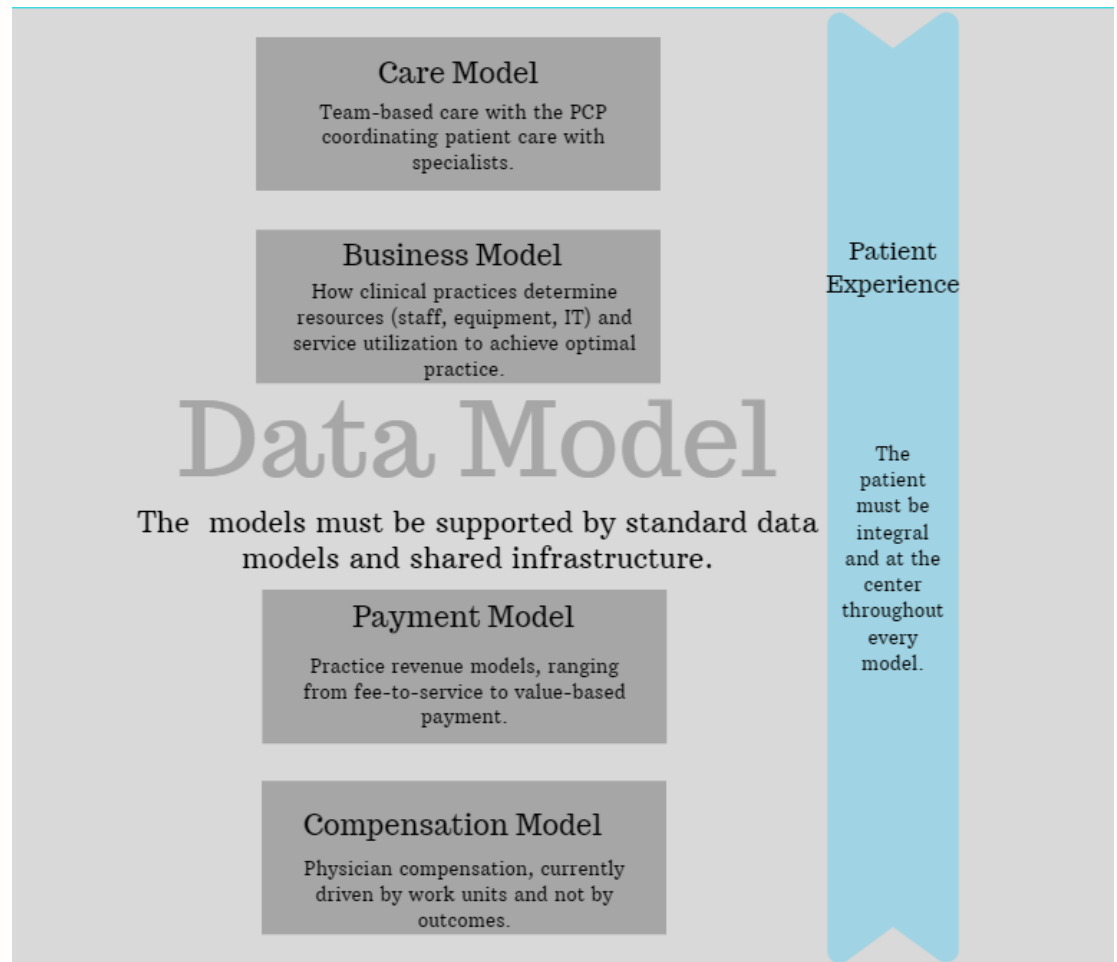Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: djohnson@facs.org

facs.org

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Care Model

Team-based care with the PCP coordinating patient care with specialists.

Business Model

How clinical practices determine resources (staff, equipment, IT) and service utilization to achieve optimal practice.

Data Model

The models must be supported by standard data models and shared infrastructure.

Payment Model

Practice revenue models, ranging from fee-to-service to value-based payment.

Compensation Model

Physician compensation, currently driven by work units and not by outcomes.

Patient Experience

The patient must be integral and at the center throughout every model.

Objective 2a: Ensure safe and high-quality care through the use of health IT

The ONC stated that advancements in health IT, specifically AI/ML, create opportunities to improve the quality of care, extend care settings beyond the traditional brick and mortar, and allow for more advanced data analytics and data sharing. The College supports these ideas and agrees that the implementation of standards lay the foundation needed for the use of more advanced health IT tools and strategies. As discussed in the *Opportunities* section, the College believes that in order to achieve the end goal of advanced health IT products integrating within daily clinical practice, it is foundational to implement a standard data infrastructure. Federal support of a vendor-agnostic, open-source patient cloud architecture would shift the industry to a patient-centric system that eases the current burdens with interoperability. The patient cloud aggregates data through a common data model to create a single, unique, and more complete patient medical record, providing physicians with the information they need to deliver the highest quality care while keeping costs low, and gives the patient agency over their own data. Grounded in standards for data exchange from the initial 21st Century Cures Act, a patient cloud could bi-directionally exchange health

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data through FHIR-based APIs between any system, including EHRs, third-party applications, registries, and wearable devices. Federal support of a patient cloud will further advance interoperability, allow for the use of more advanced technologies, and empower the patient and clinician with more accurate, current, and complete data.

As a step toward achieving data consistency and standardization within the cloud, ACS discussed recommendations for the creation of a knowledge repository on page 3, within the *Opportunities* section. The creation of such a centralized, open-source, and readily available knowledge repository would create opportunities for standardization beyond data exchange mechanisms to clinical workflows, discrete data elements, and care pathways—all of which would contribute to safe, high-quality care. Standards for both semantics and exchange will increase data liquidity and create an environment that supports the use of advanced tools. Further, standard data and large data sets allow for enhanced testing and training for these tools, especially AI and ML, which require large amounts of heterogenous data to be effective and valid.

With advanced digital health tools grounded in standards, there is the ability to extend care and treatment options beyond traditional settings. While the uptake of telehealth within the surgical care continuum has been lower than expected over the last decade, the proliferation of standards to reduce the burden of data exchange and the increase of additional third-party applications and tools will increase the propagation of telehealth solutions. For surgeons, telehealth has proven to be effective in pre-surgical assessment and post-surgical follow-ups, both in store-and-forward technology and live video streams.[5] The ACS agrees with the ONC that these technologies could be used to reach patients in rural locations, who have difficulty travelling, who have multiple chronic conditions, or who have social factors that create additional burdens or barriers to pre or post-operative care. Patient-facing applications could help patients meet post-surgical recovery goals, track progress towards those goals, share wound-care images, communicate with care teams, and conduct video visits as appropriate. Telehealth and the associated technologies can reach more patients and allow for individualized care to better meet the needs of the patient—while simultaneously reducing physician burden and increasing the flexibility of pre-and post-surgical care. It also can increase the availability of specialists and interprofessional consults, as surgeons could share data and discuss treatment options with specialists across the country.

Objective 2b: Foster competition, transparency, and affordability in healthcare

The ONC states that affordability of treatment remains a barrier for patients in seeking the care that they need, and posit that readily available information on the pricing of treatment options will allow patients to make informed decisions about care. The availability of pricing information will also foster competition, with the ultimate goal

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: djohnson@facs.org
facs.org

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[5] Latifi, Rfiat; Francisco Mora; Flamur Bekteshi; and Renato Rivera. 2014. Preoperative telemedicine evaluation of surgical mission patients: Should we use it routinely? *Bulletin of the American College of Surgeons.* https://bulletin.facs.org/2014/01/preoperative-telemedicine-evaluation-of-surgical-mission-patients-should-we-use-it-routinely/#

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of driving down costs. The College agrees with the ONC's position, and believes the real-time availability of such data in the course of care—to both the physician and the patient—will help improve quality and value of care.

The ACS agrees that price disclosure can inform and empower patients whether they shop for items and services individually or as part of service packages (i.e., individual shoppable services, explicit or implicit items within bundles, or episodes of care), and we believe that out-of-pocket cost, in addition to total cost of care, are important types of price information for patients. Furthermore, we maintain that payers—not physicians—are best suited to share out-of-pocket cost information with patients. While a surgeon or other provider may have a reasonable idea of what services are likely to be provided in conjunction with a given surgical procedure, he or she may not know, or have any influence over, who will be furnishing those ancillary services or whether that provider will be in-network for the patient. For that reason, we wish to reiterate that physicians, who are focused first and foremost on providing the best quality of care for their patients, should not be expected or required to inform patients of their out-of-pocket costs.

To enhance the usability and accuracy of these data, we encourage the Federal government and payers to utilize the open-source episode grouper maintained by the not-for-profit Patient-Centered Episode System (PACES) Center, which was officially incorporated in 2019, to create a single industry standard for defining clinical episodes of care using current medical record and payment systems and based on consensus across multiple stakeholders, including physicians, payers, purchasers, and consumers. We wish to highlight that PACES is the only episode grouper developed with inputs from all specialties, and it is continuously governed and updated to reflect care models used today.

Only with standardized logic and specifications for episodes available in the public domain can there be full transparency and a standard framework that interested parties can use to measure cost, set benchmarks, align quality metrics, and optimize value within and across systems. We believe that one open-source episode system is needed to:

- Define clinical episodes of care in a patient-centric manner;
- Better account for relevant services used to manage a patient's care for a condition or treatment;
- Promote alignment across payers' design and implementation of episode-based payment models, as well as provider's assessment of all resources needed to co-manage a patient;
- Enable consistency between payment models, costs of producing care, and performance measurement; and
- Promote the ability to identify true variations in costs and quality and establish comparisons within and across physicians.[6]

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[6] PACES Center. 2019. *A common standard for the common good.*
https://www.pacescenter.org/static/PACES%202-page%20Summary.pdf

In the complex arena of health care delivery, achieving true transparency can be challenging, especially when multiple competing definitions exist amongst stakeholders. Consensus-based, community-developed standards can reduce such complexity and create clarity about how to make comparable information available to patients in a transparent manner. This information allows for apples-to-apples comparisons, driving value-based decision making for patients in consultation with their physicians.

Objective 2c: Reduce regulatory and administrative burden on providers

The ONC notes the data and documentation requirements for reimbursement, quality reporting, and completing prior authorizations and referrals, among other regulatory and statutory requirements, creates significant administrative burden for clinicians. The ACS agrees, and further supports the strategies to reduce this burden; specifically, the convergence of clinical and administrative documentation requirements, automated tools to streamline workflows, and the harmonization of reporting requirements across programs. One of the most significant regulatory burdens for surgeons is the increased burden for administrative documentation that is clinically unnecessary due to prior authorization (PA) guidelines that are overly stringent and often inappropriately utilized. While we recognize that utilization review tools such as PA can sometimes play a role in ensuring that patients receive clinically appropriate treatment while controlling costs, many of these requirements are applied to services performed in accordance with an already-approved plan of care. **The College strongly believes this area is time-sensitive and necessary in order to decrease the overwhelming administrative burden of PA requirements and to maintain beneficiary access to a broad range of services under the Medicare Advantage (MA) program.** PA burden is largely attributable to the lack of a uniform format for the submission of PA information. To facilitate uniformity, we urge CMS to finalize Attachment Standard 278—a type of electronic transaction that physicians and facilities may use to ask an insurer to review proposed services for a given patient in order to obtain an authorization for such services—and issue model PA forms to be utilized in conjunction with MA plans' PA websites or other data entry systems. We also ask that PA requirements be made available online or in EHRs at the point of care to provide physicians with the real-time coverage information they need when making treatment decisions.

As clinical and administrative convergence is listed as a strategy in this plan, and a focus of one of the ONC's Advisory Sub-Committees, adjusting the PA requirements through standardization and a move to an electronic transaction is a tangible step that can be taken to achieve this objective.

Similarly, automated tools, including CDS, AI, and ML, can reduce the time physicians spend documenting within the EHR. The College believes that these tools hold great potential for improving clinical documentation processes and workflows, particularly when grounded in standard data elements and standards for data exchange. However, the technology must be trusted by clinicians for it to be utilized and

contribute to the reduction of burden. Therefore, we echo the need for a certification process for these technologies as discussed in the *Opportunities* section on page 4.

Lastly, the multitude of quality reporting programs that each have different reporting requirements and measures create a documentation burden on clinicians. Today, clinicians participate separately in quality measurement reporting programs, unrelated to patient care, resulting in a fragmented system with metrics that are disconnected from the patient experience. Because of this, metrics cannot be aggregated to inform patients or clinicians about the quality or price of care. What matters to patients and clinicians is safer, efficient, and high-quality care. The current programs today miss this mark, and do not contribute to improving value. Adjusting reporting programs to meet the above criteria, that conforms to the clinical care model rather than forcing clinical care to adjust to payment and regulatory needs, must be a priority across Agencies.

To incentivize high value care (higher quality at lower costs), ACS Quality Programs[7] have demonstrated that quality must be thought of as a cohesive **program** built on a four-part model that includes: 1.) program-specific quality standards, 2.) infrastructure and resources needed for the delivering high–quality care, 3.) data collection and its use to inform care delivery and improvement, and 4.) verification site visits to ensure implementation of the critical elements for optimal care.

 ACS quality program standards are designed to build team-based care around surgical conditions and unite the pre-facility, intra-facility, and post-facility care teams into a cohesive quality program focused on the patient's goals of care. **Having verification as the center of a value-based care program will result in a carefully designed quality program built on evidence-based standards.** Components critical to a quality program can be expressed as a cohesive system, including proper structure (infrastructure) and processes within systems for human factors/systems engineering, and data management for reliably tracking outcomes as part of an improvement cycle.

Importantly, quality programs must be integrated within semantically standard clinical workflows to collect meaningful data at the point of care. To be meaningful and effective, measures must reflect patient-centric, team-based care models driven by condition, creating actionable data that can be used for surgical quality improvement. For patients to assess overall value, measures must further align with patient goals, including a price that accounts for quality and cost in a team-based episode. Until this is achieved, value of care from a patient perspective will remain out of reach, and reporting programs will require additional documentation that is unnecessary, resulting in undue burden.

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[7] American College of Surgeons. *Quality Programs.* https://www.facs.org/quality-programs. Accessed on March 18, 2020.

Goal 3: Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation

The third goal in the strategic plan, **build a secure, data-driven ecosystem to accelerate research and innovation,** refers to ONC's belief that the increased data that will result from digital health standards and increased uptake of digital health technologies has great potential to accelerate research and innovation. ONC outlined two objectives to meet this goal: advance individual and population level transfer of health data; and support research and analysis using health IT and data at the individual and population levels.

Objective 3a: Advance individual and population level transfer of health data

ONC states that standards-based APIs are "key to building an integrated ecosystem that can support research, clinical decision making, population health management, and individual access to quality and cost information." The ACS supports the proliferation of standards-based APIs, as well as the creation of a common data vocabulary and standardized clinical workflows, including associated data elements. Semantic interoperability must occur alongside standards-based data exchange in order to increase the amount and types of data that can be shared. Additionally, a vendor-agnostic, open-source patient cloud architecture would further move the system towards a patient-centric, care-based environment with reduced interoperability burdens. The ACS believes that federal support and governance of such a cloud, similar to the Sequoia Project or the DaVinci project, will facilitate the shift to a cloud-based environment that can support data libraries of knowledge artifacts, ranging from clinical workflows and evidence-based best practices to specific data elements, such as LOINC or ICD-10 codes. This type of environment will improve the integrity and consistency of available data, increasing its efficacy in medical research and for the development and training of advanced technologies, such as AI/ML software.

Objective 3b: Support research and analysis using health IT and data at the individual and population levels

The ONC notes that a large amount of generated health data can be "ethically leveraged for disease prevention, quality improvement, and outcomes research." The College agrees that the increased exchange of health information will greatly expand opportunities for research and the development of advanced technologies. To realize the opportunities for research and analysis using HIT, standardized data capture in structured formats is required. This would create common data models for knowledge artifacts that could be delivered bi-directionally with and between EHRs and other health IT tools and applications. When data capture structures are consistent across formats and mediums, and use open standards, the availability and integrity of data is greatly enhanced.

The increased access to health data, coupled with the standardization and consistency of data, can greatly expand clinical research. Increased data availability and

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accessibility will allow for large scale observational studies that could dramatically increase and diversify clinical research. An accompanying goal to standardized data entry and more accessible and diverse data should be to have ways to standardly share the knowledge gained from these trials with the larger clinician community, in order for advances to improve care for all patients across populations. When standardized data entry and available datasets allow for both increased diversity in participants and widespread knowledge sharing among clinicians and researchers, advances in basic and clinical science will be greatly accelerated.

Goal 4: Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure

The fourth and final goal, **connect healthcare and health data through an interoperable health IT infrastructure,** is central to achieving all the previous goals in this strategic plan. The ONC writes that an interoperable system forms the bedrock for an ecosystem that is capable of seamless, patient-driven data exchange, and is integral to the use of advanced technologies and future innovation. ONC developed four objectives related to this goal: advance the development and use of health IT capabilities; establish transparent expectations for data sharing; enhance technology and communications infrastructure; and promote secure health information that protects patient privacy.

ACS agrees in the foundational importance of interoperability, and that the following specific actions will aid in reaching this goal: a centralized patient cloud; standards for documentation and exchange (e.g., FHIR-based APIs); privacy and security protections updated for the modern technological landscape, with a certification process as an interim solution; patient empowerment through patient-facing tools, goal-setting, and PROs; actionable quality data for physicians without additional required documentation solely for reporting purposes; and an ecosystem grounded in care models, centered around patient and condition-specific clinical needs, rather than reimbursement. These strategies can be implemented within the objectives of this goal, as well as within prior-discussed goals and objectives.

Objective 4a: Advance the development and use of health IT capabilities

The ACS agrees with the ONC that in order for health IT to continue to advance that stakeholders must have both trust and confidence in the tools. As discussed in previous goals and objectives, the ACS believes developing trust in products is best achieved through a certification process that ensures clinical accuracy and technical validity of the products, as well as enforces privacy protections. In order to encourage uptake and advanced use of trusted tools and products, the ACS believes that the federal government should incentivize use, particularly for early adoption.

The ACS also believes it is critically important that the Promoting Interoperability (PI) program becomes more than digitally specified measures for payment programs and moves beyond EHR-based conceptions of interoperability. The functionality for digitally enhanced data aggregation for payment performance measures should

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: djohnson@facs.org
facs.org

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become a **minimum standard** for health IT. To truly promote interoperability, the federal government must incentivize the use of enhanced digital health IT capability. This level of interoperability is critical in order to achieve the goal of value-based care. This will require the creation of a patient cloud where data can be processed, converted, and normalized, allowing for a digital transformation of knowledge—not simply the digitization of a paper record. Components of interoperability foundational to achieving value-based care include:

- **Incentivize bi-directional data exchange with patient cloud(s) built on open-source standards-based architecture through attestation.** This cloud-based architecture will send and receive data to and from EHRs, third-party applications, registries, Health Information Exchanges (HIEs), and patient-generated health data (PGHD). We encourage bi-directional exchange with a patient cloud environment to be incentivized across federal payment programs for clinicians and their use of health IT. Similar to above, this attestation could also advance to a scaled attestation as the use of these tools matures.

- **Establish neutral governance of architecture and standards to ensure vendor-agnostic solutions and to avoid intellectual property being owned by single vendors.** The federal government should work to develop and maintain a neutral governance of open-source standards through a public/private partnership, similar to Logica Health (formerly the Health Services Platform Consortium) or the Sequoia Project. The Sequoia Project will develop and enforce the Common Agreement for data exchange through the Trusted Exchange Framework and Common Agreement (TEFCA).

- **Identify alternatives to a Universal Patient Identifier (UPI) to ensure appropriate patient matching and increase patient safety**. Inaccurate patient matching leads to endless patient safety concerns, and enhanced interoperability will only increase these risks. In the absence of a legislative fix mandating the creation of a UPI for this issue—which is the ideal solution—we encourage the federal government and the private sector to continue to explore alternative solutions for this problem. A standard algorithm hosted in a cloud platform that assesses and determines patient matches based on identifying information, such as name, date of birth, payer ID, or other unique identifiers could be a stop-gap solution.

Through the above incentivized components and national standards for data exchange, physicians will be able to improve quality and advance care through the access to more complete and integrated patient information, and benefit from the insights gained through processing and translation of data that can occur within the patient cloud platform. This advanced model of interoperability allows for the digital transformation of data into knowledge and insights, as it is able to take in huge amounts of data, process it, display it, and share it with a variety of different endpoints and systems. These data could inform and enable a culture of continuous quality improvement focused on providing high-value care. With these components, healthcare will be

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: djohnson@facs.org
facs.org

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poised to advance its use and integration of digital tools, making the use of "big data," AI/ML, and Internet of Things (IoT) a possibility.

Objective 4b: Establish transparent expectations for data sharing

The ONC believes that one of the current burdens preventing the exchange of health data stems from information blocking. The recently published final 21st Century Cures Rule from the ONC clarifies information blocking practices and associated exceptions. The College believes that these changes will help address technical and systemic obstacles to interoperability, and appreciates the clarification that clinicians can inform patients of possible privacy and safety risks that may come from sharing their health data with an application that may have unsafe data sharing or storing practices. We also appreciate ONC's acknowledgment that health IT developers, as well as certain providers (e.g. hospitals), are in a unique position to control access to and use of EHI. Despite rights afforded under HIPAA, patients still struggle to access their health information, to transfer their records from one provider to another, and to access all of their health information in one place. Physicians also continue to face significant challenges related data access, including EHR vendors "locking-up" data in non-transferable formats or charging excessive fees to establish interfaces that allow physicians to use their own data in an intelligible manner, or to share their data with another EHR system or clinical data registry. Hospitals and health systems also often interfere with the sharing of data through contractual arrangements or by inappropriately claiming the need to comply with the HIPAA Rules. In light of these ongoing challenges, we thank ONC for tackling both technical obstacles, as well as systematic obstacles to interoperability such as information blocking.

The ACS urges ONC, along with other relevant agencies and departments, to help ensure that physicians are well-educated on what constitutes information blocking and the best practices to securing and exchanging patient health information, as well as to ensure that access is only granted to those who should have access. Given the new policy and the associated penalties, it is important that physicians and patients understand how to navigate data exchange and what constitutes information blocking, as well as how to report instances of information blocking. As discussed in previous goals, the ACS believes that centralized and shared patient-consent tracking would help ensure that patients understand who they are granting access to, and how much of their data they are consenting to share, as well as help clinicians be sure that consent is in place before exchanging data with third-parties.

Objective 4c: Enhance technology and communications infrastructure

The ONC states that eliminating disparities in access to broadband and to the technologies that are needed to run and operate advanced health IT must occur in order for there to be equitable utilization of these advancements. The ONC states that cloud-based services are an important strategy to meet this objective, as they will modernize and streamline the manner in which health data is stored, accessed, and exchanged. The College agrees, and has been a long-time proponent of cloud-based services both for the storage and the vehicle for the exchange of health information.

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: djohnson@facs.org
facs.org

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Federal support of a vendor-agnostic, open-source patient cloud architecture would shift the industry to a patient-centric system that eases the current burdens with interoperability. The patient cloud aggregates data through a **common data model** to create a single, unique, and more complete patient medical record, providing physicians with the information they need to deliver the highest quality care while keeping costs low, and gives the patient agency over their own data. Federal support of a patient cloud will further advance interoperability, allow for the use of more advanced technologies, and empower the patient and clinician with more accurate, current, and complete data. It is conceivable that multiple vendors could implement a common architecture and share across platforms. Individual commercial platforms which conform to a standard common data model can also add their own services as an overlay to meet the various needs in their markets. Without an open-source cloud platform and common data model, the industry will remain siloed, limited by costly proprietary solutions to data exchange and aggregation.

Objective 4d: Promote secure health information that protects patient privacy

The ONC believes that individual's personal health information must be protected from misuse and threats, including cybersecurity attacks, fraud, and other harms. As discussed throughout this document, and detailed on page 5 in the *Opportunities* section, the College strongly believes that privacy and security regulations and protections must be updated to meet the modern health IT landscape. Given the advances in health IT and the standards within the 21st Century Rules, the legal tensions between health privacy laws and the advancing health IT ecosystem are coming to a head. While the 21st Century rules went a long way to push technology and create national standards to remove barriers to exchange, they did not address all of the newly created privacy and confidentiality issues, or the associated patient safety concerns. As the types of mediums that can contain protected health information (PHI) expand, existing HIPAA regulations do not cover these new entities. For patients, this means that if they consent to share their health information with a third-party application or wearable device—such as MyHealth for iPhones, a FitBit, or an application that provides preventative care reminders—that these third-parties have no obligation under HIPAA to protect PHI. As the law stands today, these third-parties are under no obligation to protect or retain confidential health data; they could sell this information, and it could then be used in detrimental ways, unrelated to patient care. There are already examples of this happening: several third-party applications that individuals used to track menstruation and determine ovulation cycles have sold data to Facebook for targeted advertising, even before users consented to their privacy standards—which are *not* equivalent to HIPAA standards.[8]

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[8] Baca, Marie. 2019. "These apps may have told Facebook about the last time you had sex." The Washington Post. https://www.washingtonpost.com/technology/2019/09/10/these-apps-may-have-told-facebook-about-last-time-you-had-sex/. Accessed March 18, 2020.

This gulf in the landscape could result in patients being hesitant to use new technology to better understand and manage their care, in clinicians struggling to balance the need to comply with federal data sharing requirements while also minimizing potential downstream patient safety and privacy issues, and with the industry creating advanced digital health tools that cannot yet be utilized to their full potential. As such, while privacy legislation needs to be updated, federal agencies and departments should implement a certification process for technology in the interim to ensure the tools used are not only clinically accurate, but also technically valid and safe. In order to empower patients, patients must trust that their data is protected, will not be used inappropriately, and that the clinical information that they are receiving is accurate and appropriate.

The discussed certification process and prior recommendations will help bring patient privacy protections into the modern digital age without hamstringing health care from adopting and utilizing tools that could bring positive change into the sector. Because technology is changing so quickly, it is important that policy does its best to keep pace with the changes. New digital tools will continue to disrupt and challenge the health care industry, and policy or practice that puts privacy at risk should not stymie the potential of these new innovations. The federal government should work with both technology vendors and health care providers on a consistent basis to maintain solutions that better align with the health information technology ecosystem of the future, and keep patient privacy—and empowerment—at the forefront.

Thank you for the opportunity to provide feedback to the ONC's 2020-2025 Federal Health IT Strategic Plan. The ACS looks forward to working with the ONC and other federal agencies to further the vision detailed throughout this comprehensive plan. Please contact Jill Sage at jsage@facs.org or (202) 672-1507 if you have any questions or need additional information.

Sincerely,

David B. Hoyt, MD, FACS
Executive Director

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org

Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: djohnson@facs.org

facs.org

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