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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: ahp@facs.org

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January 28, 2019

Don Rucker, MD

National Coordinator for Health Information Technology

Office of the National Coordinator for Health Information Technology

U.S. Department of Health and Human Services

330 C Street, SW

Washington, D.C. 20201

RE: Strategy on Reducing Regulatory and Administrative Burden
Relating to the Use of Health IT and EHRs

Dear Dr. Rucker:

The American College of Surgeons (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. On behalf of the over 80,000 members of the ACS, we appreciate the opportunity to submit comments to the Office of the National Coordinator for Health Information Technology (ONC) on its draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, published on November 28, 2018.

The ACS puts the welfare of our surgical patients above all else, and we support policies and regulations that promote high-quality care, reduce the regulatory burdens placed on physicians, and streamline clinical workflow. As the ONC and Department of Health and Human Services (HHS) engage in efforts to leverage health information technology (HIT) and electronic health records (EHRs) to eliminate unnecessary administrative barriers to the provision of medical services, we believe that it is critical for physicians to be involved in such activities. The College, with its 100 year history in establishing standards for the national improvement of surgical care, stands ready to collaborate with the ONC to work towards interoperability that serves not only to ease documentation burdens, but also to inform patient care.



OVERVIEW OF REGULATORY AND ADMINISTRATIVE BURDEN

Physicians today are inundated with a growing number of administrative requirements set forth by Congress, Federal agencies, and insurers, often adding needless obstacles to providing timely, high-quality services and increasing spending on non-clinical activities. Surgeons find themselves spending more time completing paperwork in order to demonstrate regulatory compliance, taking them away from what is most important—their patients. HIT and EHRs have the potential to dramatically reduce workflow inefficiencies and improve care delivery, quality, and outcomes; however, the administrative burden associated with the use of HIT along with usability hurdles prevent physicians from capitalizing on the benefits of these technologies.

An additional challenge is that the complexity of modern medicine has exceeded the ability of a single physician to provide all the care that a patient requires because there are limits to the amount of information one can process. The clinical care model is growing increasingly complex and the need for digital information to flow between all members of a team is critical to successful patient care and prevention of medical error. Such data must be captured or documented digitally, but also must be synthesized and represented back to the provider in a convenient and usable format. Delivery systems, in turn, are expanding in complexity. Figure 1 below illustrates the complexity of a delivery system today and the overwhelming number of entities with which the delivery system (shown in green) must interact and seamlessly share data.

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

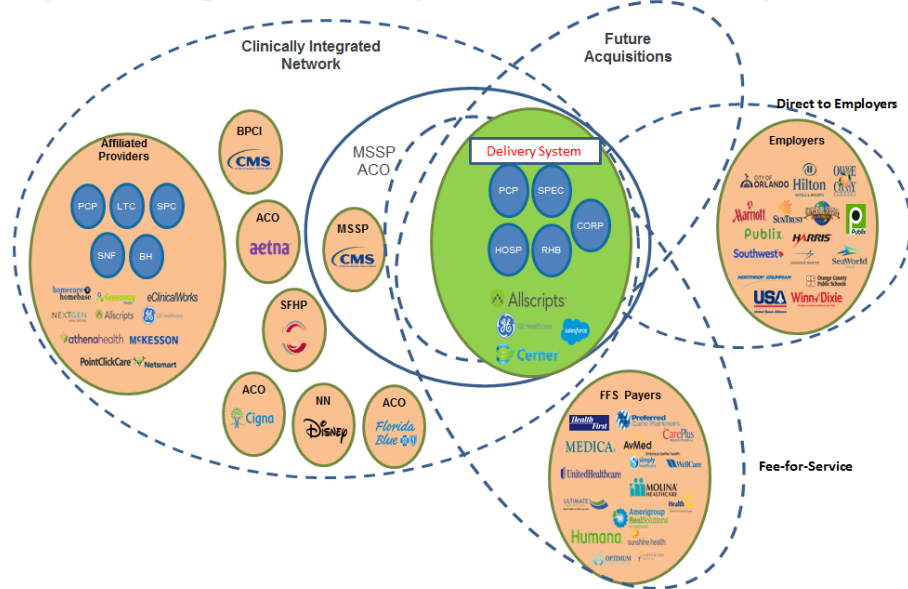
E-mail: ahp@facs.org

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Figure 1. Complexities of the Typical Care Delivery System

Typical Delivery System Reality: Expanding Landscape & Complexity



Without access to interoperable and usable digital health information, providers and other members of the delivery system spend hours documenting and searching for information, which is extremely burdensome. In addition, without interoperability, providers lose the opportunity to truly leverage health care data available in the entire clinical data ecosystem to enhance algorithms of care and treatment plans, analyze outcomes of therapy, and track resources.

The ACS believes that there are a number of actions the ONC can take to more effectively utilize information accessible through an interoperable digital health information system that serves not only to ease documentation burdens, but also to inform care through clinical decision support (CDS) tools and eventually through more advanced technologies such as machine learning and artificial intelligence. The challenges associated with the use of HIT and EHRs today, along with the impediments to such technologies reaching their full potential as part of a fully interoperable health system, are complicated by a number of factors,



which we address in our feedback below. Our comments are presented in the order in which they appear in the ONC draft strategy.

CLINICAL DOCUMENTATION

Strategy 1: Reduce regulatory burden around documentation requirements for patient visits

- ***Recommendation 1: Continue to reduce overall regulatory burden around documentation of patient encounters. As discussed in the calendar year (CY) 2019 Medicare Physician Fee Schedule (PFS) final rule, CMS intends to reduce burden associated with physician payments under the PFS starting in 2021 by paying a single payment rate for several levels of office-based/outpatient evaluation and management (E/M) visit codes, thereby enabling a minimum documentation standard for the majority of office/outpatient visits billed to the PFS. CMS also finalized a series of add-on codes that will be used instead of multiple code levels to distinguish different kinds and lengths of E/M visits within these levels.***

We appreciate the attention and efforts of the ONC and the Centers for Medicare & Medicaid Services (CMS) to reduce regulatory burden around documentation of patient encounters. As we stated in our comment letter to the CY 2019 PFS proposed rule, we do not support the approach of creating a single payment rate and add-on codes for certain E/M office/outpatient visits. We strongly urge CMS to consider alternative proposals regarding these issues that are introduced through the proceedings of the CPT Editorial Panel and the AMA/Specialty Society Relative Value Scale Update Committee, and we ask that the Agency not move forward with the single payment rate and add-on code policies as finalized for CY 2021.

- ***Recommendation 2: Leverage data already present in the EHR to reduce re-documentation in the clinical note. Many EHRs simply translate a paper-based documentation workflow into an electronic one. This limits the ability of technology to leverage information that may exist elsewhere in the HIT system. As a***

Chicago Headquarters

633 N. Saint Clair Street
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Fax: 312-202-5001

E-mail: postmaster@facs.org

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Voice: 202-337-2701

Fax: 202-337-4271

E-mail: ahp@facs.org

facs.org



result, many pieces of information that clinicians enter into their clinical notes already exist in other places in the EHR. Over time, modern computing resources could allow developers to innovate new ways to determine visit complexity beyond what is present in the clinical note. This could also facilitate a review and verification process for existing information that is seamless for the end-user, while allowing for audit functionality.

The ACS is in full agreement that use of EHRs alone, especially those that simply translate paper-based documentation workflows into electronic ones, severely limits the ability of clinicians to utilize digital health information. An essential point to stress is that data liquidity extends beyond a clinician's EHR and into a patient's consolidated medical record. The complete set of patient data then becomes available for a range of applications or services, thereby enabling a knowledge representation wherever needed. As such, Recommendation 2 should be broadened beyond just leveraging data already present in EHRs to instead harness all digital health data.

Information that has been previously captured in an EHR, or is available from another digital source should be easily accessible and available to populate the most complete representation of a patient's current medical record. The ability to efficiently find and utilize existing patient information is the single biggest step that can be made today toward reducing documentation burden. The critical next step is the ability to create relevant knowledge from digital services such as CDS aids. These aids are based on computer algorithms such as relevant cancer guidelines and necessary treatments and tests, to enhance patient care and decrease both documentation burden and clinician burden. Any data verification mechanisms that are contemplated for the future should not only confirm that the data are correct but that they are current.

Both the technology and the tools exist today that can be used toward this goal. One example, developed by HarmonIQ Health Systems, is ClinIQ, which a provider dashboard that allows clinicians to access data aggregated from a range of clinical data sources, including multiple EHRs, as well as state and regional health information exchanges. The ClinIQ dashboard is made up of a selection of widgets that display relevant

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: ahp@facs.org

facs.org



information for the patient. The representation of data is highly customizable, which makes significant strides toward reducing burden. Other companies such as Medal and The Meges Health Group are working on similar solutions that could reduce burden associated with data located in multiple sources. In Meges, data represent the complete knowledge about a patient undergoing a surgical procedure and are visible through a surgeon platform, a nurse platform and a patient platform. This allows for coordination of care with engagement of the entire team. Giving patients and the surgical team a trusted digital environment focused on the care model is a welcome reduction in burden from the EHR world and creates a safer, high quality environment for care.

We encourage the ONC to consider other sources of representing and recording information beyond just EHRs. Specifically, we ask that ONC work with both EHR vendors and technology developers to support the development and widespread use of other kinds of technologies such as portals and dashboards, and to support the use of open standards in transmitting information between EHRs or other digital sources. Certain types of information cannot be properly captured and used in an EHR. For example, the Meges Group has developed a tool that will manage a patient's peri-operative medications and provide notifications to the patient and provider as to when the patient should reduce or stop taking certain medications prior to surgery. A patient undergoing a surgical procedure who is currently medicated with anticoagulants needs to have timely disruption in their medication prior to their operation. Such digital services can enable better, safer care. This critical information should be captured and incorporated into the story of the patient's care along with data from the patient's EHR.

We also believe that data should be shared in a way that is usable for the recipient, be it an EHR vendor, another type of vendor that is running an app, or the patient. It is not enough that data be transferred in a way that only EHRs can accept. To achieve this, the industry must create both clinical and technical digital standards for patient information to smoothly interoperate and be represented in a clinical workflow within and between EHRs and all the locations where patient data reside. Access to relevant information extracted and displayed in a user-friendly manner from large

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: ahp@facs.org

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repositories of clinical information then brought together at the point of service not only reduces documentation burden, but also makes great strides toward improved patient care, patient safety, and reduced clinician burnout.

- **Recommendation 3: Obtain ongoing stakeholder input about updates to documentation requirements.** *HHS should continue to receive wide stakeholder input to inform future documentation guideline modifications. Stakeholders have suggested that a representative task force would be useful given the widespread uses of medical record information by clinicians of all specialties, public and private payers, EHR vendors, and others. Clinical specialty societies could continue to provide input to define proper clinical standards for documentation and establish what is required for high quality patient care.*

Modifications to documentation guidelines should not take place without nationwide stakeholder input. There should be an open and transparent process for reviewing draft changes with enough time for specialty societies to review and provide feedback. HHS should consider alternatives presented by specialty societies and not move forward with proposed modifications that receive a high degree of concern or opposition from the medical community. If created, a representative task force on medical record information should include patients as well as clinicians, payers, EHR vendors, and others. Requiring clinical specialty societies to provide input to define proper clinical standards for documentation may not be feasible given that what is considered “proper” could vary based on the patient, but defining minimum documentation standards would be more practicable.

- **Recommendation 4: Waive documentation requirements as may be necessary for purposes of testing or administering APMs.** *CMS recently piloted a program to reduce medical review burden for alternative payment models (APMs). APMs can provide powerful motivation to deliver care in the most efficient manner possible, and CMS intends to further explore reducing APM burden by waving certain documentation requirements for APMs.*

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633 N. Saint Clair Street
Chicago, IL 60611-3211

Voice: 312-202-5000

Fax: 312-202-5001

E-mail: postmaster@facs.org

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Washington, DC 20001

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Fax: 202-337-4271

E-mail: ahp@facs.org

facs.org



The primary purpose of documentation is to generate a patient-focused record. It is to leverage the digital environment to capture and represent data needed to best serve the needs of patient care. Documentation also serves as a means of communication for the physician to record information for himself/herself and to communicate information to the patient and other clinicians who interact with the patient. There are several secondary purposes of digitally documenting in a patient record. Secondary purposes include making data available for CDS, for registry feeds, for quality metrics and in support of payment. Once knowledge is captured once, it should be available for use at multiple points, without being subject to cut and paste redundancies. APMs are innovative payment models, so waiving documentation requirements to alleviate burden specifically associated with APMs would primarily aid testing and implementation of APMs rather than promoting patient-focused documentation. Waiving documentation requirements should primarily focus on optimizing care. Using these waivers to incent interest in a payment program would suggest that the payment program lacks value to stand on its own merit.

The ACS believes first in design of optimal care models, next in leveraging clinical informatics to optimize care and finally to create sustainable payment models which supports the two previous points. The path noted in Recommendation 4 suggests the payment model is unfit on its own and needs other props to draw in surgeons. ACS would suggest many surgeons are very ready for alternative payment models. Our work on adoption to APMs is based on the design of optimal care models, clinical informatics, measurement, and asymmetric risk based contracting which would incent movement to APMs without distortions to documentation.

Strategy 2: Continue to partner with clinical stakeholders to encourage adoption of best practices related to documentation requirements

- ***Recommendation 1: Partner with clinical stakeholders to promote clinical documentation best practices. Best practices for clinical documentation in EHRs could reduce duplicative***

Chicago Headquarters

633 N. Saint Clair Street
Chicago, IL 60611-3211

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Fax: 312-202-5001

E-mail: postmaster@facs.org

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Washington, DC 20001

Voice: 202-337-2701

Fax: 202-337-4271

E-mail: ahp@facs.org

facs.org



documentation among care teams and template-driven “note bloat.”

Development and adoption of best practices for clinical documentation in EHRs is challenging due to the complexity of the care environment and complexity of care needed for each individual patient. But we believe that the ONC should continue to explore this recommendation. For example, best practices for blood pressure would vary depending on the care environment so attempting to define what is a meaningful blood pressure measurement is not straightforward and could result in a very broad range. Examples of documentation best practices that are valuable, on the other hand, would be documentation of medical decision-making and care plan/goals. Regardless of how ONC moves forward with this recommendation, any documentation best practices should not be mandatory or restrict a clinician’s workflow. As noted above, there are opportunities to create documentation dashboards including best practices using widgets and apps.

Strategy 3: Leverage HIT to standardize data and processes around ordering services and related prior authorization processes

Surgeons across the country are facing setbacks in furnishing services to patients due to prior authorization processes that are antiquated, overly stringent, and inappropriately utilized by insurers. While some aspects of the clinical workflow have become automated, prior authorization remains a manual, paper-based task for many physicians. The exorbitant amount of time and resources practices must devote to prior authorization is due in part to the lack of automated prior authorization processes that integrate with medical record systems. The encumbrance of inefficient prior authorization requirements represents unnecessary hours of lost clinical productivity, increased practice costs, and delays or interruptions in medically-necessary treatment.

The College strongly believes that ONC intervention in this area is time-sensitive and necessary in order to decrease the overwhelming administrative burden of prior authorization and to maintain patient access to timely care. We ask that these issues be addressed by taking the actions described in our comments 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: ahp@facs.org

facs.org



- ***Recommendation 1: Evaluate and address other process and clinical workflow factors contributing to burden associated with prior authorization. HIT-enabled processes that leverage existing data within the medical record could decrease the total volume of prior authorization requests that clinicians must submit.***

To better integrate prior authorization into the clinical workflow and prevent associated patient harm, the ACS believes that all processes needed to obtain prior authorization for medical services should be made available in EHRs or other digital technologies at the point of care to provide physicians with the real-time coverage information they need when making treatment decisions. We recommend that the ONC support leveraged patient and payer data in EHRs to notify physicians of prior authorization requirements when ordering a service, automate prior authorization decisions for routine therapies, and pre-populate prior authorization documents for cases in which further review is needed. The use of information already stored in EHRs to complete prior authorization processes could streamline payer-provider communication, improve the accuracy and efficiency of these non-clinical tasks, and ensure the timely provision of care. We encourage the ONC to take a leadership position in the development of standards for HIT-enabled prior authorization, and to work with organizations already experienced in this area—such as AIM Specialty Health, which enables completion of prior authorization and provides real-time payment clarity and clinical determination in EHRs through its AIM Inform tool—to obtain additional expert guidance on integrated prior authorization solutions.

The College commends the ONC’s focus on advancing standard electronic approaches to automated prior authorization, but we also urge the agency to consider non-digital process flaws. These could be remedied by actions such as

- (1) **limiting the scope of prior authorization requirements to physicians whose ordering practices stray (below a preordained threshold) from evidence-based medicine or suggest a pattern of overutilization;**
- (2) prohibiting prior authorization for services that are standard for a specific condition, are part of an ongoing therapy regimen, exhibit

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: ahp@facs.org

facs.org



low variation in utilization or denial rates, or have been approved previously as part of a patient's care plan; and

- (3) eliminating trivial barriers to payment in order to guarantee reimbursement for a service performed that is clinically comparable to an approved service but is more accurately reported using a different current procedural terminology (CPT) code, or when a particular service's necessity was not anticipated and/or the service was performed incident to, or during the course of, an approved procedure.

We believe the preponderance of payer activity in prior authorization has significantly overburdened clinicians and added to the overall cost of care. The impact of prior authorization is disruptive to a clinical practice and its ability to meet patient needs due to all the time spent on administrative functions of prior authorization. These burdens are further compounded by the complexity model as shown in Figure 1 on page 3. If each payer were to implement their own set of rules for prior authorization, this serves to overwhelm a clinical practice. Either more payer resources are needed to afford these new burdens and the associated increase in practice overhead, or a standardized set of rules must be created and applied in executable code for all payers to use. ACS stands ready to work with CMS, ONC, and organizations such as AIM Specialty Health to create such an industry standard.

- ***Recommendation 2: Support automation of ordering and prior authorization processes for medical services and equipment through adoption of standardized templates, data elements, and real-time standards-based electronic transactions between providers, suppliers, and payers. Expanded utilization of HIT solutions to automate prior authorization processes could reduce the administrative burden associated with completing clinical documentation required for justifying medical necessity when ordering certain services and/or obtaining prior authorization.***

The administrative burden of prior authorization processes is in part attributable to the lack of a standard format for the submission of clinical documents. To facilitate uniformity, we urge ONC to assist CMS in finalizing Attachment Standard 278—a type of electronic transaction that

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: ahp@facs.org

facs.org



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 ask that this standard include a single format for the submission of supporting clinical documentation, as well as a single secure digital envelope for data communication and encryption. We believe that such an electronic clinical attachment standard could significantly reduce clinician time spent complying with each payer’s unique prior authorization requirements.

- ***Recommendations 3 and 4: Incentivize adoption of technology which can generate and exchange standardized data supporting documentation needs for ordering and prior authorization processes; work with payers and other intermediary entities to support pilots for standardized electronic ordering of services. Offering incentives to use HIT for prior authorization processes could relieve clinician burden and provide standardized documentation. Facilitating stakeholder participation in pilots to standardize electronic ordering could accelerate adoption of these functionalities.***

While the ACS supports efforts to encourage the adoption of electronic prior authorization, we wish to highlight that the automation of such processes cannot entirely eliminate the administrative hassles associated with prior authorization. The College believes that, if automated prior authorization technology is incentivized and implemented by CMS but is not similarly utilized by private payers, physicians will still be required to navigate various forms of documentation submission and prior authorization requirements throughout the entire insurance industry.

If the ONC were to engage payers in the testing of automated prior authorization pilots, we think that it is critical for all pilot participants to test the same standard technology, as well as to document the extent of their use of prior authorization and their approval/denial rates by service under such technology. Participants should be required to report data on the specific services subjected to prior authorization, the proportion of each service granted authorization, and the time elapsed from submission until the issuance of an organization determination. The ONC should also consider how to incorporate the role that genomics can play in

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: ahp@facs.org

facs.org



authorization decisions, and we assert that prior authorization pilots should include clinical decision support (CDS) for alternative options in the case of denials. The ACS believes that an ONC-private payer collaboration has the potential to identify areas for improvement in prior authorization programs and processes that, once implemented, can achieve meaningful reform.

We also think that any successful pilot program must also consider the concerns of all stakeholders, and we urge the ONC to not only conduct piloting with payers, but also with physicians whose practice workflows are impaired by prior authorization requirements. The College asks that participation in the ONC's pilot program be voluntary for the physician community to ensure that no additional administrative or financial burdens are placed on practices that may not be readily equipped to test new technologies. We also do not believe that testing automated prior authorization through APMs would be the ideal sandbox because it would not be representative of all users of prior authorization and efficiencies might not be scalable.

- ***Recommendation 5: Coordinate efforts to advance new standard approaches supporting prior authorization. Consensus-based standards should be developed to support multi-payer, real-time prior authorization and reduce provider burden.***

The ACS urges the ONC to incorporate the following three activities in its efforts to standardize and automate prior authorization to achieve scientific rigor and regulatory relief: (1) base PA logic on prevailing evidence- and consensus-based guidelines from clinical experts, and publish such logic as an open standard with a public comment period, (2) facilitate the development and utilization of CDS tools using Fast Healthcare Interoperability Resources (FHIR) application programming interfaces (APIs) for the purposes of digitizing and automating prior authorization within EHRs, and (3) encourage all payers to use the same open standards and electronic services for prior authorization in order to avoid both the imposition of different prior authorization logic from each insurer, as well as confusion related to compliance with multiple payers' prior authorization requirements in the clinical setting. We believe that AIM Specialty Health's AIM Inform tool, which eliminates the need for

Chicago Headquarters

633 N. Saint Clair Street
Chicago, IL 60611-3211

Voice: 312-202-5000

Fax: 312-202-5001

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Washington Office

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Voice: 202-337-2701

Fax: 202-337-4271

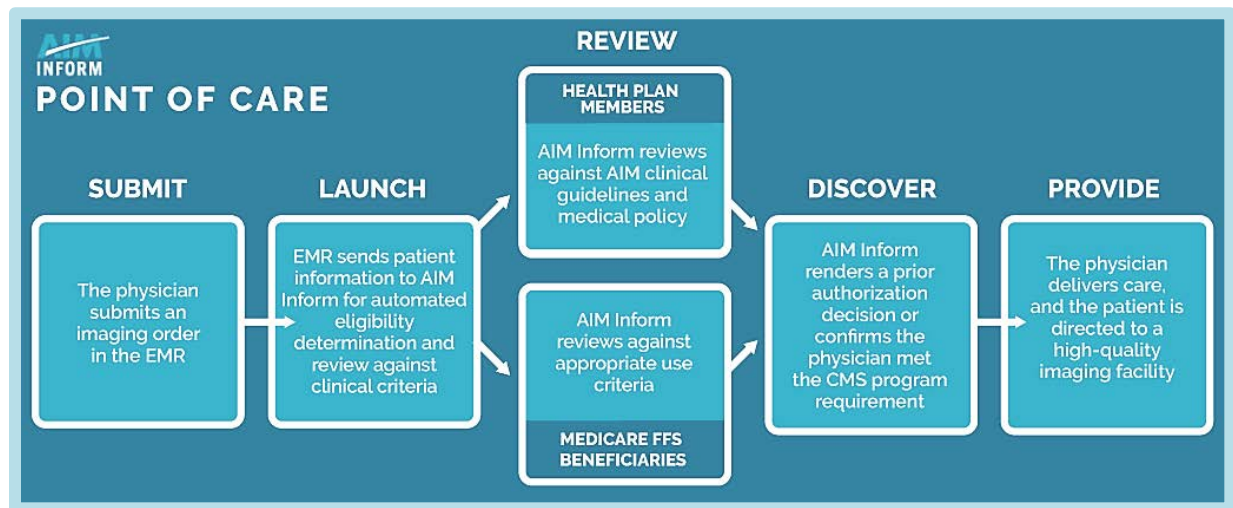
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physicians to use separate technologies to fulfill prior authorization and CMS billing requirements, is one such example of an effective model to unify multiple components of the clinical workflow (see Figure 2).¹

Figure 2. AIM Inform Logic Model



HEALTH IT USABILITY AND THE USER EXPERIENCE

Strategy 1: Improve the usability through better alignment of EHRs with clinical workflow; improve decision making and documentation tools

- **Recommendation 1: Better align EHR system design with real-world clinical workflow.** HIT developers can take the lead by working with practicing clinicians, nurses, laboratorians, administrators, and professional organizations who can advise developers as they make decisions and prioritize interactive display features during development to streamline workflow. Achieving a balance between standardization and customization is important.

As mentioned above, patient data should be accessible from data sources beyond just EHRs, including registries, performance measurement, smart

¹ AIM Specialty Health. (2018). Payment Clarity at the Point of Care. *AIM Inform*. Retrieved from <http://www.aimspecialtyhealth.com/Solution-AIMInform.html>



devices, medical devices, research data systems, pharmacy data, and more. There is great value in harnessing data sources beyond just EHRs. For example, Megees Health Group has developed a product to capture detailed patient information such as the phases of surgical care, medication list, day the patient took a bath, etc. This critical information is not recorded in EHRs. As such, we support recommendation 1, but it should go one step further to take additional forms of useful technology into consideration when working to improve alignment with clinical workflow because alignment of EHRs and other devices is needed to most impact patient care.

Standards are also needed to enable the various technologies and tools to interact. Standards for how to define data, the value sets for the data, and the data models needed should be developed by technical experts such as those with expertise in HL7, Fast Healthcare Interoperability Resources (FHIR) and open application program interfaces (APIs). We support the development and use of open standards architecture with reference architecture that interacts with overall interoperating knowledge clouds. Although this recommendation states that achieving a balance between standardization and customization is important, we ask ONC to keep in mind that innovation can arise from customization and open standards.

- **Recommendation 2: Improve clinical decision support usability.** *The appropriate application of data standards and applications that associate critical clinical information data elements is essential to providing high quality care. There is tremendous opportunity for CDS to be improved and augmented beyond alerts to include predictive care suggestions to help make decisions at the point of care.*

We agree that the potential of CDS extends far beyond pop ups and alerts. Instead, use of CDS is most powerful by way of widgets incorporated into apps and provider dashboards that aggregate patient data from a range of clinical data sources specific to a condition or disease. Such clinical specialty portals when used at the point of care, can truly leverage CDS.

CDS is only as good as the clinical logic and the technology behind it. For that reason, the CDS tool must be vetted to assure that the clinical logic is

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: ahp@facs.org

facs.org



sound and meaningful. Development of clinical logic models requires understanding the details of clinical care and mapping them to specific computable terminologies. We believe that the clinical experts are best positioned to develop and maintain such clinical logic models. CDS tools must also be vetted to assure that the technology, which should be developed by technical experts, is true to the clinical logic (for example, pulling the correct data, running it correctly, etc.). A sandbox is needed to test the CDS tool or app to make sure that it performs correctly. We encourage ONC to work with developers to create a repository of tested CDS tools that would be available for public use.

- ***Recommendation 3: Improve clinical documentation functionality.*** Current EHR documentation tools take the form of free text entry, template completion, and use of buttons and structured data fields. Less burdensome methods to capture both the structured and unstructured data inherent in a patient's medical story are needed. HIT developers can consider collaborative partnerships with large healthcare institutions to improve their speech recognition capabilities through machine learning to shed light on EHR workflows that can be optimized.

As we discussed above, we urge ONC to expand the EHR-centric focus of these recommendations to improve ease of documentation in any tool or device where patient data may reside and be utilized. Also, as discussed above, we support the development and use of provider dashboards that display relevant condition or disease-specific information for the patient through the use of widgets. This information is aggregated from all the various sources of patient data, not just one or more EHRs. Ideally, ONC should work with EHR vendors and other developers to enable FHIR write capability to truly move toward a standards-based interoperable digital health information system that serves not only to ease documentation burdens, but also to inform care. Use of these dashboards or portals would go further toward improving clinical documentation functionality than simply improving speech recognition.

- ***Recommendation 4: Improve presentation of clinical data within EHRs.*** HIT developers can reduce cognitive load on clinicians by improving information display for the end user.

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: ahp@facs.org

facs.org



We urge ONC to consider all relevant patient data and how it can be displayed, not just improvements to presentation of clinical data within EHRs. Please see Clinical Documentation, Strategy 1, Recommendation 2, above.

Strategy 2: Promote user interface optimization in HIT that will improve the efficiency, experience, and end user satisfaction.

- ***Recommendation 1: Harmonize user actions for basic clinical operations across EHRs. EHRs have widely divergent GUIs and workflow steps required to complete clinical tasks. EHR developers could standardize a number of functionalities (results review; medication reconciliation; medication, laboratory, and image ordering; problem list interaction; medical history interaction; and clinical documentation authoring and review).***

We support the standardization of certain functionalities for EHRs, but we stress that these standards should be applicable beyond EHRs as well. Our work with the Healthcare Services Platform Consortium (HSPC) is a pathway to achieving this goal. We agree that in order for common clinical workflows to turn into executable workflows, standards are needed. In order to create standards, repositories of open source common logic models are required. HSPC is currently working to create clinical logic models that can then be mapped to specific computable terminologies. The objective is to develop a repository of logic models that would serve as one of the foundational elements for building the digital components of a learning health system. Once the logic data are defined by FHIR resources, anyone could build a FHIR profile and use the logic model in an app. Such a use case repository would serve as a first step toward building the infrastructure for standards-based interoperability. We also stress the need for reference architecture as the digital infrastructure of a learning health system develops.

- ***Recommendation 2: Promote and improve user interface design standards specific to health care delivery. There is currently variable adherence to usability best practices among EHR products. This makes it difficult for end users to perform common workflow tasks and may increase clinician frustration. User***

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: ahp@facs.org

facs.org



interfaces should support clinicians' cognitive thought processes and EHR developers can create a shared repository of usability best practices and support of clinician's cognitive thought processes.

We agree that user interface design standards should be improved for EHRs. We have commented in previous letters to HHS that EHRs do not adequately align with clinicians' thought processes and workflows. We encourage HHS to examine products developed by companies such as Meigs Health Group and Medal, which have incorporated user-friendly platforms.

- ***Recommendation 3: Improve internal consistency within HIT products.*** *Software developers can review their suite of software solutions to ensure that all aspects of the system share a common user interface and style guide.*

We support this recommendation provided there is a clinical need for internal consistency of HIT products. Too much standardization can inhibit customization and innovation, so there should be some connection to a clinical need or improvement of patient care.

- ***Recommendation 4: Promote proper integration of the physical environment with EHR use.*** *Health care institutions should keep in mind EHR usage and clinical team interaction when designing the physical space.*

We support this recommendation, but are not able to provide further comment because it is beyond our area of expertise. Experts in the design of healthcare institutions should be consulted for this topic.

Strategy 3: Provide harmonization surrounding clinical content contained in HIT to reduce burden.

- ***Recommendation 1: Standardize medication information within HIT***

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: ahp@facs.org

facs.org



We generally support this recommendation, but standardization should keep the end user in mind and overregulation should be avoided. Medication information should include whether or not the drug is on the patient's formulary, the total cost of care, and the patient's cost per their plan. CDS should be included about alternatives specific to the patient's formulary. We also believe that some form of patient portal representation (beyond EHRs) of drugs to the patient is necessary.

- ***Recommendation 2: Standardize order entry content within HIT***

Rather than attempting to refine definitions for unique imaging tests, we urge HHS to first focus on creating standard definitions for common imaging tests. But these definitions should allow for adaptations because strict standards could potentially stifle innovation.

- ***Recommendation 3: Standardize results display conventions within HIT***

As ONC has mentioned previously, standards must be balanced by the need for customization. We believe that basic core sets of clinical results should be standardized. These include: urine analysis, metabolic profile, liver profile, complete blood count, and specialty. But the end user should have the capability to assemble these core pieces in a customized way that is tailored to his or her needs.

Strategy 4: Improve HIT usability by promoting the importance of implementation decisions for clinician efficiency, satisfaction, and lowered burden.

- ***Recommendations 1: Increase end user engagement and training.***
- ***Recommendation 2: Promote understanding of budget requirements for success***
- ***Recommendation 3: Optimize system log on to reduce burden***
- ***Recommendation 4: Continue to provide nationwide strategies that further the exchange of electronic health information to improve interoperability, usability, and reduce burden.***

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: ahp@facs.org

facs.org



Recommendation 1 relies heavily on EHRs to increase end user engagement and training. We urge ONC to include all useful and relevant forms of digital health technology in this recommendation for increased end user engagement and training as integral components of the overall picture of the patient's healthcare data. We support recommendation 3 as an important way to reduce provider burden, and we particularly support the use of facial recognition software for optimizing system log on. We also support recommendation 4 and we agree that to leverage digital health information for better care will require partnership between government and the commercial sector in the form of open standards and overcoming proprietary barriers. We stress again that the full picture of digital health information is needed, not just fully functioning and usable EHRs. To truly harness the power of digital health information, different clinical platforms and patient portals are needed to generate the right knowledge at the right time and represented in the right way for the right reasons. Also needed is a trusted verification ability to vet clinical logic models and their technical implementation. Strong government support is needed to build the infrastructure for standards-based interoperability.

EHR REPORTING

Strategy 1: Address program reporting and participation burdens by simplifying program requirements and incentivizing new approaches that are both easier and provide better value to clinicians.

- *Recommendation 1: Simplify the scoring model for the Promoting Interoperability performance category.*

ACS supports a patient-centric focus when considering the role of HIT in quality measurement, Promoting Interoperability (PI), and improvement activities. Making these programs meaningful to the care delivered and within the clinical workflow is consistent with reducing the burden of these HIT objectives. When the programmatic goal is not aligned with patient care, and only serves to score in a payment program for an insurer, federal regulations become a distraction to care and are burdensome. ACS believes the first step in combining QPP action items into a burdenless solution requires that they are tied into a common data model which focuses on the patient. In this model, interoperability is the first and most crucial step. Surgeons will act upon the data which best represents the

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: ahp@facs.org

facs.org



patient under their care. Unfortunately, the EHRs today lack interoperability to provide aggregation of the critical patient information upon which clinicians act. The EHRs only collate information from the local digital environment and do not collate all the knowledge necessary to care for a patient adequately. Thus, continued over-reliance by CMS or ONC on EHRs will add to the burden when it comes to measuring true quality and driving real improvement.

Measuring true quality and driving real improvement are the next areas of focus when reducing burden. The current set of CMS quality measures are not meaningful to surgery because they do not align with surgical workflow or measure key events across an episode of surgical care with patient-reported outcomes. Therefore, the measures are inherently a burdensome and are only valued for the purposes of payment. It would be disingenuous to support HIT or interoperability which only promotes ease in reporting of underperforming quality measures. It certainly reduces the burden in the reporting function to aggregate e-measures, but it does little for the patient by distracting surgeons from true quality.

The same is true for improvement activities. Quality measurement and improvement are inextricably linked. Improvement will come by virtue of meaningful measurement. However, defining explicit improvement activities for an individual is difficult when the improvement rests on a team's performance on behalf of a patient. Overly prescriptive improvement activities tend to rely on typical, repetitive missteps which occur during the course of care. Real improvement tends to be more nuanced or unique to each care team's setting. Trying to capture these activities within an EHR environment is very challenging and may be more siloed than intended by the QPP designers.

So, how does ACS think about these three elements of QPP (Interoperability, Quality and Improvement) in a perfect world?

- (1) First, focus on the patient and not the technology in EHRs.
- (2) Next, consider meaningful quality performance measures which inform improvement activities for a full cycle of improvement.

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: ahp@facs.org

facs.org



- (3) Then, thread these into the fabric of a digital representation using technology, but not limited to EHRs.

Focus on the patient and not the technology in EHRs. As we have stated in the previously, patients do not live in single EHRs—surgeons try to construct their knowledge of a patient from all information sources. ACS is increasingly hearing from the field about the limits of EHRs and the start or emergence of cloud-based representations of a patient. These representations are based on a higher order of interoperability of information which has been built into a new common data model upon which patient representations occur. These efforts may exist in a cloud or even in a registry. We believe ONC should accept these efforts of patient-level constructs as a form of interoperability which may rival the commonly sought efforts of EHR-to-EHR/ point-to-point solutions. As long as these data more wholly reflect the patient in a common data model, they become the interoperable source of truth. Once this exists, it is possible to examine the quality of care and drive improvement. If an EHR can fulfill a whole-view of the patient, we can accept EHRs as interoperable and enabling for quality and improvement.

Consider meaningful quality measurement which informs improvement activities. Few CMS measures are true surgical quality measures are therefore considered burdensome. Instead, most of CMS measures capture events such as morbidity and mortality outcomes—we agree these are important, but rare. Functional outcomes such as episode-specific patient reported outcomes are true quality measures which are valued by patients and the surgeon. A digital environment which seamlessly measures these functional outcomes and picks up the morbidity and mortality outcomes from a clinical registry across an episode of care are the centerpieces to quality outcome measurement. Again, if these functionalities are intrinsic to EHRs, then ONC can tag EHRs for their ability to perform these functions. However, that seems unlikely in the current EHR data models and functionality.

As we have mentioned previously, improvement is inextricably linked to quality measurement. Thus, if the quality tool measures functional outcomes, morbidity and mortality, the improvement activities tend to measure the structural components and processes of the care teams. ACS

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: ahp@facs.org

facs.org



has over a century of experience in measuring quality and driving improvement. There are common aspects across all surgical care as well as nuanced or unique aspects in structural and process elements in surgical care design. Optimal surgical care calls for appropriate preoperative preparation and planning, while intraoperative efforts also influence outcomes. Post-operative recovery and rehabilitation are also both generic and specific. For example, most patients need preoperative medication assessment and management or postoperative pain control. And, episode or procedure-specific improvement activities would differ substantially for a joint replacement versus someone undergoing an intracranial operation or major, complex gastrointestinal surgical care. Enhanced Recovery After Surgery (ERAS) protocols are important clinical improvement plans which consider the complexity of patient care in order to optimize outcomes. These are examples of common elements to consider in improvement activities for surgical care.

Do not limit the flow of the digital representation of a patient to EHRs.

Ideally, a digital information system should enable a representation of the complete patient and their surgical care journey. To achieve this calls for a common data model built on interoperability standards canonically. These models are slowly emerging in the field. ACS would seek ONC's role in accelerating these actions. We would also expect that EHRs should assist in these efforts, avoid data blocking and even consider their own ability to contribute to these models, with a requirement to be accepting of open APIs.

There are a few examples of how CMS and ONC can help prioritize the use of common data models built on interoperability in the QPP:

- **PI Program:** Actions taken toward the use of a common data model built on interoperability should be fully considered as meeting interoperability requirement of PI. We provide additional recommendations for how to achieve this in the PI program below.
- **Quality Measurement:** Quality measurement could be readily based on the common data models as a source for measurement in the QPP—this would be meaningful to patients and surgeons.

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: ahp@facs.org

facs.org



- **Improvement Activities:** The digital architectures would accept open APIs which could harness the structural and process aspects of surgical care improvement found in activities which could be generic to all of surgical care or nuanced to specific episode/procedures.
- **Reduce Complexity Across Delivery Systems:** Finally, something which is under appreciated by CMS and ONC is the concern ACS has heard from the ‘field’ about complexity. CMS has intended to create a myriad of options for participation in its QPP programs. We appreciate this approach, particularly when a concept is in its embryonic stages. However, with each payer designing their own solution, it is common for delivery systems to be bombarded with 10 different means for doing the same thing. The result is that the delivery systems seek the least common denominator. What gets implemented is what is simplest and not what is best for patients. The impact is that vital aspects of care are burdened or dropped in favor of payment.

We believe CMS and ONC can aid as a convener in identifying best-in-breed and valuing those aspects for interoperability, quality and improvement. ACS is prepared to assist the government agencies in these efforts as long as the focus is on the patient and their ultimate health. The focus should not be on achieving the highest level of participation in a payment program unless it is first linked to the best of care.

To this end, we strongly suggest CMS in partnership with ONC consider a new approach for the PI program to create an incentive-based, tiered scoring methodology which rewards the bi-directional sharing of patient-centric information and functionality across the digital ecosystem. The tiers can be divided into four general categories, starting with EHR interoperability, with data streams moving bi-directionally across EHRs, mobile devices, registries and clouds where the data can be used to support CDS, and eventually result in artificial intelligence or computer adaptive learning:

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: ahp@facs.org

facs.org



- (1) EHR ↔ EHR
- (2) EHR ↔ EHR ↔ mobile device
- (3) EHR ↔ EHR ↔ mobile device ↔ registries/clouds with Clinical Decision Support guidelines
- (4) EHR ↔ EHR ↔ mobile device ↔ registries/clouds with Clinical Decision Support guidelines ↔ machine learning / artificial intelligence

To achieve this, CMS and ONC must work together to address the significant shortcomings of the PI performance category, starting with a more robust set of objectives and measures that capture actual functions of interoperability across multiple disparate providers, patients and systems. We have the following recommendations:

- (1) **CMS should collaborate with the ONC to aid specialty medicine and other stakeholders in the process of creating clinical conceptual models as a necessary first step toward building the technical logic models and applied terminologies and value sets needed for interoperability.** This is the process of translating clinical content in its context to enable the level of interoperability needed by the clinical team to provide the best care. Clinical knowledge can then be digitally exchanged when the computable logic models are translated into semantic interoperability. Furthermore, as clinical logic models turn into computable logic models, these should be open source for all to use and held in a public-private partnership repository. From these repositories, individuals can create APIs for exchangeable knowledge.
- (2) **To enable digital health information interoperability across EHRs, mobile devices, registries and patient clouds, the government should take a stronger leadership role in public-private partnerships to foster working relationships between clinical experts and technology experts.** This should include establishing a framework, processes, overall governance, priorities, policies, support for resources needed to convene clinical content and context expertise alongside technology and standards

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: ahp@facs.org

facs.org



expertise. The physician community, in collaboration with other stakeholders, would have a go-to home from which to select specific clinical domains to create interoperable solutions, and those domains would lead to open source interoperable digital standards.

- (3) **EHR certification standards should be created to require EHRs to be compliant with the described open source digital standards that meet criteria for clinical interoperability.** This would greatly aid in data liquidity, which would eliminate data blocking, and enable patient cloud environments.
- ***Recommendation 2: Incentivize innovative uses of HIT and interoperability that reduce reporting burdens and provide greater value to physicians.***

As discussed above, the current PI category measures focus on disparate, standalone functions of EHRs. For MIPS to truly become a quality improvement program that harnesses the functions of HIT to advance the practice of medicine, PI measures should connect to quality performance measures which then inform improvement activities for a full cycle of improvement.

ACS believes that the current QPP program is a siloed program based on legacy programs that predate MACRA, built on measures that are not meaningful to surgeons. Therefore, the current program is currently not able to measure surgical value. ACS has proposed an alternative to the MIPS program which is based on the use of verification or accreditation programs supported by the use of digital services. This alternative framework could identify failure points in care and be used proactively for corrective actions.

Our experience at the ACS is that the power in creating a culture of quality, safety, and improvement comes from a trusted set of evidence-based standards applied in a verification program, built upon high-quality, reliable data by employing the four ACS Principles for Continuous Quality Improvement: 1) tracking standards individualized to the patient and based on research, 2) using the right infrastructure including quality

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: ahp@facs.org

facs.org



processes, checklists, equipment and staffing/specialists 3) rigorous attention to highly reliable data, including post-discharge tracking and 4) verification of overall program implementation at the point of care with an external peer-review process which creates public assurances. This framework could act as a paradigm for all surgical quality measurement by ensuring surgeons have meaningful measures that are relevant to their patients and their practice, drive improvement towards better patient outcomes, and minimize the burden of data collection. We believe that this framework defines healthcare value in a patient-centric way based on episodes of care with intent to represent accountability across a clinical domain. **Critical to this framework is the digital health infrastructure required to allow data to flow between providers who treat a given patient.**

ACS proposes that the MIPS score could be based on the three components of how ACS defines quality. This is also illustrated in Figure 3, below. This model will need to be tested and validated:

- (1) Patient-reported Outcomes (PROs). The majority of surgical procedures are elective with the goal of improving a patient's quality of life and/or function. Therefore, for most procedures, the outcome reported by the patient and for which the patient is the best source of success of the procedure. Additionally, most elective procedures have very few serious clinical events, which highlights the fact that PROs can be used to distinguish variability across clinicians and groups. ACS is working with clinical experts from the Brandeis University, Brigham and Women's Hospital, and University of Rochester Medical Center to deploy our quality measurement prototype for improving measures in patient reported outcomes for surgical care. We believe this framework could generate comprehensive assessments of surgical quality encapsulating both surgeons' and patients' perspectives across episodes of surgical care.
- (2) Participation in a Standards-based Verification Program. Our experience at the ACS is that the power in creating a culture of quality, safety and improvement comes from a trusted set of

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: ahp@facs.org

facs.org



evidence-based standards applied in a verification program, built upon high-quality, reliable data.

The foundation to the ACS verification programs is based on over a century of experience in building surgical quality. The key elements are:

- i. Verification based on a focused condition or surgical procedure, which must have a care model. That care model must span the critical services within the care continuum by considering services from the onset of treatment and through recovery
- ii. A statement of commitment
- iii. Identified key leaders and committees of oversight or engagement
- iv. A defined scope and resources (A. human capital and B. physical resources)
 - v. Discrete care pathways within the phases of surgical care
 - vi. Data systems and episode-specific surveillance of outcomes
 - vii. Quality improvement
 - viii. Research and Education (optional)
 - ix. Measurement: Outcomes and Total Cost of Care (TCOC)
 - x. Enabling IT: Registry data for conformance to standards, risk adjusted outcomes and PROs. The HIT should present a dashboard for the entire episode team, patients and payers

It is well documented in the literature that conformance to evidence-based standards yields better outcomes. The PI and improvement activities requirements for MIPS could be included as standards within a verification program. For general surgery, we envision three levels of verification —Level 1, 2, and 3 which would be comparable to the process used for the ACS Trauma verification program, where nearly 250 standards and sub-standards are considered. In this example, we could identify key processes that track failure points in surgical care across an episode of care, with the use of ERAS protocols tailored to a specific case.

PI measures can be integrated into evidence-based verification programs to help track clinical quality through the use of digital services that can identify failure points and be used for corrective actions. This integration into a verification program would mean the measures for PI are part of the clinician’s workflow, reducing burden and increasing its meaningfulness.

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: ahp@facs.org

facs.org



- (3) Clinical Outcome Measures. Depending on the type of episode, this component of the score could measure accuracy of clinical outcome measures developed using claims data only, registry data only, and hybrid claims-registry data. We hypothesize that for certain operations where adverse outcomes are rare or are limited in scope, it may be possible to utilize claims data alone to validly and reliably evaluate performance; whereas, for other operations where adverse outcomes are common or can vary widely in scope, it may be necessary to utilize registry data or at least a combination of claims and registry data. For general surgery, we could determine (1) which clinical outcome measures can be accurately implemented using claims data alone to minimize burden while ensuring appropriate validity and reliability for performance assessment, and (2) which clinical outcomes measures must utilize registry data, albeit more burdensome but justifiably so.

This model relies on validation of successes by measuring outcomes using clinical data analytics which partially depend on bi-directional automated interoperability for data exchanges to and from registries. Our proposal simultaneously is integrated into surgical workflows while reducing burden by measuring compliance with standards through triennial surveys, rather than measures linked to CPT or DRG codes.

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

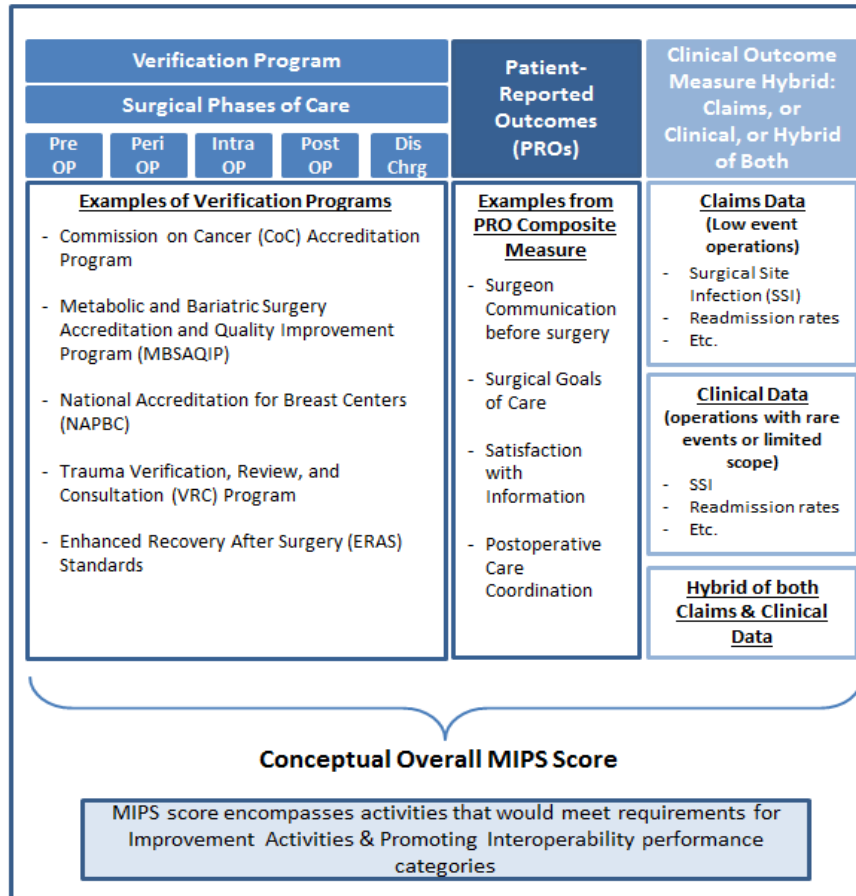
Fax: 202-337-4271

E-mail: ahp@facs.org

facs.org



Figure 3: Conceptual Framework for Measuring Surgical Quality in MIPS



- Recommendation 3: Reduce burden of HIT measurement by continuing to improve current HIT measures and developing new HIT measures that focus on interoperability, relevance of measure to clinical practice and patient improvement, and electronic data collection that aligns with clinical workflow.***

ACS believes the PI category should focus on interoperability beyond just EHRs in order to leverage digital health information from any data source, be it EHR or smart phones. EHRs currently allow end users to use “receive” functions, like reading their allergy or medication list, but there is a lack of willingness of HIT vendors to allow users to use “write” functionalities within their EHR. Data exchange starts with read functionality but must eventually have write functionality to accomplish



fully functioning interoperability. Write functionalities within the EHR allow end users to more easily add, display, and share information to other end users. **To this end, we recommend CMS and ONC adopt PI measures of functional interoperability that focus on read and write functionality in order to accomplish greater interoperability among EHRs and other HIT. One policy solution would be that write functionalities could be a standard in order to be a certified EHR technology (CEHRT) vendor.**

- *Recommendation 5: Revise program feedback reports to better support clinician needs and improve care.*

ACS has consistently heard from our members that it is very difficult to access MIPS performance feedback reports, and for surgeons who are able to access them, the reports lacked sufficient detail and actionable information. **Therefore, we strongly support the testing of an open API approach to support a consistent integrated feedback loop. It is critical to pilot test the implementation of the open API MIPS performance feedback reports prior to regulatory implementation.**

Strategy 2: Leverage HIT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs.

- *Recommendation 1: Recognize industry-approved best practices for data mapping to improve data accuracy and reduce administrative and financial burdens associated with HIT reporting.*

We encourage ONC to recognize industry-approved best practices for data mapping in order to achieve patient-centric interoperability. As stated earlier, ACS believes the PI performance category should not be confined to EHRs, but should consider the entire digital ecosystem and part of the clinical workflow. ACS encourages ONC and CMS to recognize industry-approved best practices for data mapping for patient-centric interoperability. In the recently finalized 2019 QPP rule, CMS chose not to include the patient-generated health data measure (PGHD) because they

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: ahp@facs.org

facs.org



are concerned that the burden to encourage a clinician's patients to provide data is too high a burden on clinicians. However, we believe that this measure is truly innovative in achieving the goal of patient-centric data by taking advantage of integrating data from the proliferation of smart devices, like smartphones, smart watches, and remote monitoring devices to improve patient-centered care. For example, Apple's recent efforts with their HealthKit application use FHIR resources to access an individual patient's health information on different platforms and store the information on a patient's personal smart device. That patient may use Apple compliant applications to provide representations of their personal health to them on their mobile phone.

We advise CMS and ONC to continue work in this area, as they may be able to identify how to modify this measure to better capture its intended goal. Once the measure specification issues are resolved, CMS should once again propose the PGHD measure for inclusion in the PI category.

- ***Recommendation 2: Adopt additional data standards to make access to data, extraction of data from HIT systems, integration of data across multiple HIT systems, and analysis of data easier and less costly for physicians and hospitals.***

ACS strongly supports the recommendation to adopt additional data standards to make access to data, extraction of data from HIT systems, integration of data across multiple HIT systems, and analysis of data easier and less costly for physicians and hospitals. To drive this work, we are currently working with Healthcare Services Platform Consortium (HSPC) and Clinical Information Interoperability Council (CiiC) to advance the logic models needed. HSPC and CiiC represent non-profit organizations which bring the clinical expertise and the informatics engineers to create an implementable common strategy for building use cases for interoperability. **Examples of this work include building a common set of cancer standards for staging, for stage-specific treatment, and so forth. We also are working to build the surgical risk calculator as an automated digitally interoperable tool. These efforts are predicated on HL7 standards such as using Fast Healthcare Interoperability Resources (FHIR).**

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: ahp@facs.org

facs.org



One way to describe our view of interoperability in more granular terms is to start with use cases, which are libraries of ideas that involve all aspects of care. Use cases are designed by clinicians, government agencies, and others and are placed into the cloud to improve workflow and to achieve optimal patient care. Examples of use case ideas include Clinical Decision Support (CDS), making guidelines or evidence available, automating registry exchanges, building outputs for performance measurement, and communicating across care delivery teams.

Although clinical and technical standards needed for interoperability are developed separately, the clinical experts must join with the technology experts to provide the context and contextual profiles needed for use cases and eventually to build apps. Development of clinical logic models requires understanding the details of clinical care and mapping them to specific computable terminologies. We believe that the clinical experts are best positioned to develop and maintain such clinical logic models. On the technical side, standards for how to define data, the value sets for the data, and the data models needed should be developed by technical experts such as those with expertise in HL7, FHIR, and open APIs.

Once developed, use cases can be combined into a patient specific longitudinal care use case repository with help from clinical delivery systems, government agencies, specialty societies, payers and purchasers, and patient advocates. The objective is to develop a library of use cases that can be held in a use case repository. The use case repository would serve as one of the foundational elements for building the digital components of a learning health system. The digital infrastructure of a learning health system lacks full development of its architecture, but such a use case repository would serve as a first step toward building the infrastructure for standards-based interoperability. Having a dedicated entity governing updates, availability, and version control of logic models would further promote trust and communication among stakeholders, and progress consensus-based standards for interoperability.

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: ahp@facs.org

facs.org



- **Recommendation 3: Implement an open API approach to HHS electronic administrative systems to promote integration with existing HIT products.**

Please refer to the above response in Recommendation 2.

Strategy 3: Improving the value and usability of electronic clinical quality measures while decreasing health care provider burden

- **Recommendation 1: Consider the feasibility of adopting a first-year test reporting approach for newly developed electronic clinical quality measures.**

It is critical for CMS and ONC to first focus on making sure that measures chosen are meaningful to patients and clinicians prior to adopting new eCQMs. In our experience with ACS Quality Programs including National Surgical Quality Improvement Program (NSQIP), Trauma, Bariatric, and Cancer programs, if the measure is meaningful it is not burdensome. This is the most important step in deciding which measures should be implemented on a large-scale. If this is not the priority, we will continue to perpetuate the use of meaningless data which will add to administrative burden.

The ACS appreciates the opportunity to provide feedback on this ONC draft strategy and looks forward to continuing dialogue with ONC on these important issues. If you have any questions about our comments, please contact Vinita Ollapally, Regulatory Affairs Manager, at vollapally@facs.org or Jill Sage, Quality Affairs Manager, at jsage@facs.org.

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: ahp@facs.org

facs.org