

August 25, 2017

The Honorable Patrick Tiberi Chairman Committee on Ways and Means, Subcommittee on Health U.S. House of Representatives Washington, DC 20515

Re: Medicare Red Tape Relief Project Feedback

Dear Chairman Tiberi,

On behalf of the American College of Physicians (ACP), I am writing to provide feedback on the Subcommittee on Health's Medicare Red Tape Relief Project. The College is encouraged by the Subcommittee's interest in the topic of reducing regulatory and administrative burden within the Medicare program and appreciates the opportunity to provide feedback.

The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 152,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

A list of ACP's priority areas is outlined below and described in further detail throughout the letter:

- 1. Utilize the American College of Physicians' (ACP's) Cohesive Framework to Evaluate and Publish the Impact of Government Regulations and Administrative Tasks on the Doctor-Patient Relationship and Remove Barriers that Unnecessarily Interfere with Meaningful Interaction between Health Care Clinicians and their Patients
- 2. Simplify the Merit-based Incentive Payment System (MIPS) Scoring System
- 3. Simplify the Evaluation and Management (E/M) Documentation Guidelines
- 4. Reduce Administrative Burden Associated with Billing Chronic Care Management (CCM) and Other Care Management Codes
- 5. Remove the Copayment for Chronic Care Management (CCM) Services
- 6. Simplify and Align the Quality Measurement System to Ease the Burden of Reporting, Enhance Patient Care, and Build a Learning Health Care System

- 7. Align Varying Policies, Procedures, and Contracting Arrangements in the Medicare Advantage (MA) Program with Traditional Medicare to Promote Transparency and Reduce Excessive and Burdensome Administrative Tasks
- 8. Promote Practical Interoperability/Specific Query Functions of Patient Information
- 9. Reduce the Burden of Public Health Reporting
- 10. Promote a National Initiative that Uses a Common Set of Data Elements to Match a Patient to his/her Individual Electronic Health Information and Study the use of a Voluntary Universal Unique Healthcare Identifier
- 11. Implement the Appropriate Use Criteria (AUC) without Imposing Undue Administrative Burden on Participating Physicians

### Priority #1:

# **Short Description:**

Utilize the American College of Physicians' (ACP's) Cohesive Framework to Evaluate and Publish the Impact of Government Regulations and Administrative Tasks on the Doctor-Patient Relationship and Remove Barriers that Unnecessarily Interfere with Meaningful Interaction between Health Care Clinicians and their Patients

### **Summary:**

The growing number of administrative tasks imposed on physicians and patients adds unnecessary costs to the U.S. health care system. Excessive administrative tasks divert time and focus from more clinically important activities of physicians and their staffs, such as providing actual care to patients and improving quality, and may prevent patients from receiving timely and appropriate care or treatment. In fact, the literature has consistently found that time spent by clinicians and their staff on billing and insurance-related activities is about 3 to 5 hours per week, and time spent on quality measurement and reporting activities is potentially up to 15 hours per week. In addition, administrative tasks are keeping physicians from entering or remaining in primary care and may cause them to decline participation in certain insurance plans. They're also a major contributor to the "physician burn-out" epidemic.

These tasks can stem from federal health care requirements, as well as from private payers, vendors, and suppliers. Often administrative tasks are added without any formal assessment of why the task is being proposed, what is intended by the task, and its actual impact on physicians and patients (such as diverting physicians from spending time with patients to complying with unnecessary administrative tasks), and whether the tasks could be eliminated,

<sup>&</sup>lt;sup>1</sup> Casalino LP, Nicholson S, Gans DN, Hammons T, Morra D, Karrison T, et al. What does it cost physician practices to interact with health insurance plans? Health Aff (Millwood) 200928w53343

<sup>&</sup>lt;sup>2</sup> Morra D, Nicholson S, Levinson W, Gans DN, Hammons T, Casalino LP. US physician practices versus Canadians: spending nearly four times as much money interacting with payers. Health Aff [Millwood)201130144350

<sup>&</sup>lt;sup>3</sup> Sakowski JA, Kahn JG, Kronick RG, Newman JM, Luft HS. Peering into the black box: billing and insurance activities in a medical group. Health Aff (Millwood)200928w54454

<sup>&</sup>lt;sup>4</sup> Casalino LP, Gans D, Weber R, Cea M, Tuchovsky A, Bishop TF et al. US physician practices spend more than \$15.4 billion annually to report quality measures. Health Aff (Millwood)2016354016

streamlined, or modified to reduce the burden on physicians without harming quality, safety, or program integrity.

# **Related Regulation:**

Update the regulatory impact analysis for both new and existing regulations associated with administrative tasks in health care.

#### **Proposed Solution:**

ACP urges Congress to call on the Centers for Medicare and Medicaid Services (CMS) to incorporate into the regulatory impact analysis a standard assessment of cost, time, and quality of care for public review and comment. These analyses should occur for existing and new regulations and associated administrative tasks. Those regulations and tasks that are determined to have a negative effect on quality and patient care, unnecessarily question physician and other clinician judgment, or increase cost should be challenged, revised, or removed entirely. In a recent position paper, Putting Patients First by Reducing Administrative Tasks in Health Care, ACP proposes a cohesive framework for analyzing administrative tasks to better understand any given task that a clinician and his/her staff may be required to perform and then potentially be revised or removed entirely, by government and other external entities. The College strongly recommends Congress call on CMS to consider using this framework for identifying and classifying new or existing requirements or tasks and incorporate the following questions into the regulatory impact analysis:

- a. Could the requirement interfere with or enhance the ability of clinicians to provide timely and appropriate patient care (both in-person and remotely, in real time and asynchronously)? What are the expected or potential opportunity costs of the requirement in terms of its effect on time spent by clinicians providing care for patients and on any time spent by patients to address the requirement?
- b. Does the requirement improve the quality of care delivered to the individual patient and/or to the population? If so, how?
- c. Does the requirement have a financial impact on the physician practice, provider organization, patient and his/her family, and/or the health system that diverts resources from patient care? To what extent can this impact be quantified?
- d. Does the requirement call into question physician judgment in terms of expertise, training, education, and experience? If so, what are the reasons these questions are being raised?
- e. Overall, can stakeholders propose alternative approaches to accomplish their goal for consideration by the public?

# Additionally, ACP recommends Congress:

- Urge the Administration to convene a multi-agency task force to obtain input from clinicians and review evidence to identify administrative tasks that could be streamlined or eliminated, based on the detailed framework discussed above and in our policy paper. Agencies to consider including in the multi-agency task force: Department of Health and Human Services (HHS), HHS Office of the Inspector General, CMS, Center for Medicare and Medicaid Innovations (CMMI), Office of the National Coordinator for Health IT (ONC), CMS Program Integrity Office, CMS Medicare Advantage Offices, Office of Personnel Management (OPM), Department of Defense (DoD), and Department of Veterans Affairs (VA).
- Facilitate Congressional hearings among government agencies, clinician stakeholders, and electronic health record (EHR) vendors to foster collaboration among parties requiring everyone to recognize their role and responsibility in reducing administrative burdens to improve patient care.

Call on federal advisory bodies, including the Medicare Payment Advisory Commission (MedPAC), to research the effect of administrative tasks on patient and family care experience and outcomes.

### Priority #2

# **Short Description:**

Simplify the Merit-based Incentive Payment System (MIPS) Scoring System

#### **Summary:**

When Congress sunsetted the payment adjustments associated with Physician Quality Reporting System (PQRS), the value-based payment modifier, and the EHR Incentive Program through MACRA, the intent was that these programs would be rolled into one streamlined program – MIPS – that combines the piecemeal approach to assessing clinicians into a single program with a single payment adjustment attached to it. CMS made modifications to the overall scoring methodology through rulemaking; however, ACP still has concerns with the scoring structure for MIPS, including proposed revisions, because overall it continues to allow each performance category to operate within its own fragmented silo. Most significantly, there are still different scoring systems across the performance categories, and while all of this may have been well-intentioned, the inconsistent construction adds significant and unnecessary complexity to the already complicated Quality Payment Program (QPP).

# **Related Regulation:**

In the 2018 QPP Proposed Rule, CMS proposes modifications to the methodology to create a final MIPS composite performance score (CPS):

• Zero out the weight of the Cost Performance Category – which was initially set at ten percent of the overall CPS for 2018.

- Increase the weight of the Quality Performance Category from 50 to 60 percent of the CPS.
- Increase the overall performance threshold for the CPS from three points to 15 points, which fails to align sufficiently with most participation options for the 2018 performance period.
- Add a complex patient bonus of 1-3 points based on average HCC risk score.
- Add a small practice bonus of 5 points for practices with 15 or fewer ECs that submit data in at least one performance category.
- Propose a methodology for scoring improvement in the quality and cost performance categories.
- Create a lower scoring standard for quality measures that are identified as topped out, allowing them a maximum of 6 points rather than 10.
- Allow 1 point for failing to meet data completeness criteria for quality measures, while allowing small practices 3points.

ACP recommends that Congress call on CMS to simplify the MIPS scoring system via the following approaches (additional QPP recommendations can be found in our <u>Comment Letter</u> to CMS Regarding MACRA/Quality Payment Program (QPP) Proposed Rule for CY 2018):

- Further simplify and standardize the scoring approach within MIPS in order to allow the
  point value for each measure or activity to be fully reflective of its value within in the
  overall composite performance score (CPS). Currently, there is still a different
  methodology for the weight of points in each performance category that does not fully
  align with the value of the category in contributing to the overall CPS. Alternatively, ACP
  proposes that CMS modify the point values to reflect a more unified approach:
  - The available points within the quality component should add up to a total of 60 points counting for 60 percent;
  - The points within improvement activities would add up to 15 counting for 15 percent;
  - The points within ACI would add up to 25 counting for 25 percent (and not 155, with only 100 of those points actually "counting," as described in this proposed rule); and
  - When cost is eventually recalculated into the overall CPS, the points would add up to however much it is weighted in the overall score (10 points if 10 percent; 30 points if 30 percent).
- Modify the base score component of the Advancing Care Information (ACI) performance category and remove the threshold requirements of 1 or "yes" for all proposed base measures except for the protecting patient health information attestation, which ACP believes is integral to the use of health IT. When considering our move to a value-based and learning health care system and exploring ways to further advance the use of health IT, there is an opportunity to be less prescriptive.

- Continue to consider additional options in rulemaking to promote taking on quality improvement activities that crossover into multiple performance categories to strengthen MIPS and make the program more comprehensive rather than siloed.
- Remove the weighting of Improvement Activities, as it adds unnecessary complexity and it is unclear what evidence might indicate why certain activities might be considered medium versus highly weighted.

# Priority #3

# **Short Description:**

Simplify the Evaluation and Management (E/M) Documentation Guidelines

### **Summary:**

The Evaluation and Management (E/M) documentation guidelines that were devised in the early 1990's provide guidance on what clinicians must document to bill for a particular code level of visit. The problem is that they specify the required contents of the medical record in excruciating — and often irrelevant — detail. The detailed guidelines often cause clinicians to over-document, making the medical record an ineffective source of communication. To address the elements specified in the guidelines, some clinicians are tempted to engage in extraneous clinical activity to justify using higher code levels.

Moreover, the E/M codes themselves are a "one size fits all" set of codes used by all the specialties of medicine. They are premised on taking an extensive history from the patient and performing a physical examination. Caring for patients with multiple chronic illnesses does not require repeated, extensive physical exams or the taking of a traditional history once the information is initially captured. Examinations may be brief and focused and the history may revolve around functional issues. For cognitive specialties, the intensity of the visit requires making complex medical decisions for their patients. The E/M documentation guidelines as currently defined do not capture the work involved with this type of care in our modern era.

### **Related Regulation:**

The Evaluation and Management Comment Solicitation in the CY 2018 Physician Fee Schedule Notice of Proposed Rule Making

Current Evaluation and Management Documentation Guidelines:

- The 1995 Documentation Guidelines for Evaluation and Management Services: <a href="https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/95Docguidelines.pdf">https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/95Docguidelines.pdf</a>
- The 1997 Documentation Guidelines for Evaluation and Management Service: <a href="https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/97Docguidelines.pdf">https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/97Docguidelines.pdf</a>

ACP recommends that Congress call on the Centers for Medicare and Medicaid Services (CMS) to remove the history and physical exam requirements of both the 1995 and 1997 E/M documentation guidelines. Once those requirements are removed, medical specialty organizations can work with the Agency to create a specialty-specific framework for the five levels of existing E/M codes that include general principles of care for each level of E/M code. These principles would incorporate the medical decision making portion of the 1995/97 guidelines in order to have the clinical documentation also tied to program integrity and auditing practices. Electronic health record (EHR) vendors would be required to build in an attestation based on the principles of care for each specialty. Clinicians would write their clinical note based on the established patient care principles for the specialty and the information captured within the EHR would be tracked to support the care delivered by the clinician.

# Priority #4

### **Short Description:**

Reduce Administrative Burden Associated with Billing Chronic Care Management (CCM) and Other Care Management Codes

# **Summary:**

In CY 2015, CMS implemented separate payment for CCM services that incorporated many service elements and billing requirements that the physician or non-physician clinicians must satisfy in order to fully furnish these services and report these codes. These elements and requirements were relatively extensive and generally exceeded those for other E/M and similar services. CMS has recognized through comments from numerous professional societies and underutilization of the codes that some of the service elements and billing requirements are too burdensome. However, ACP members continue to report that they do not participate in the CCM program because of the onerous administrative burden and those who do participate in the program still feel that administrative burdens are too high. In the CY 2018 Physician Fee Schedule (PFS) proposed rule, the Agency is soliciting feedback on how to further reduce the burdens associated with CCM and other care management service codes.

### **Related Regulation:**

The Care Management Comment Solicitation in the CY 2018 Physician Fee Schedule Notice of Proposed Rule Making

### **Proposed Solutions:**

The CCM payment system should allow for and promote non-visit based management between visits, time spent where time is needed, but also a less costly low-touch approach that helps to keep the majority of patients in contact with the health system where needed, but without necessitating expensive one-to-one care. **ACP recommends that Congress call on CMS to implement the following solutions:** 

- Clarify that the CCM planning code (G0506) can be billed on a day separate from an E/M
  date of service. The rationale is that for many situations where the physicians know the
  patient well, they may perform or develop the chronic care plan on a day different from
  when they enroll the patient.
- Allow that a properly done Annual Wellness Visit, with all of the required elements, along with a review of the chronic medical conditions, can count as a Chronic Care Plan as long as it was done within the past year.
- Simplify the documentation requirements required to bill CCM services as opposed to requiring physicians document each separate minute of care management over the course of the month. There is a significant resource cost involved in maintaining time logs to demonstrate 20 minutes of time over the course of a month for a specific subset of physician's patient panel that is enrolled in the program.

## **Priority #5**

# **Short Description:**

Remove the Copayment for Chronic Care Management (CCM) Services

#### Summary:

The College believes that CCM services are generally consistent with the types of additional preventive services that are appropriate for Medicare beneficiaries and should not have a copayment associated with the provision of service. The copayment associated with enrollment in the CCM program provides a cost burden on patients in need of these preventive services and additional administrative burden for physicians and their staff to collect this separate copayment on a monthly basis.

In particular, we believe that CCM services meet the requirements of section 1861(ddd)(1)(A) of the Social Security Act because the services are specifically designed to prevent chronic conditions from advancing into chronic disease stages. Additionally, the College believes that CCM services are appropriate for individuals entitled to benefits under part A or enrolled in Part B, and thus meet the requirements of section 1861(ddd)(1)(C) of the Act. Since CCM services have not received a recommendation with a grade of A or B by the U.S. Preventive Service Task Force (USPSTF), they do not meet the requirement in section 1861(ddd)(1)(B) of the Act and have not be added to the list of "additional preventive services." However, under Section 1115A(d)(1) of the Act, the Secretary has authority to waive certain requirements and we propose using this waiver authority to waive Section 1861(ddd)(1)(B) of the Act with respect to CCM services.

#### **Related Statute:**

Section 1115A(d)(1) of the Social Security Act provides a description of the waiver authority for Additional Preventive Services: "The Secretary may waive such requirements of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) as may be necessary solely

for purposes of carrying out this section with respect to testing models described in subsection (b)."

# **Proposed Solutions:**

ACP strongly recommends that Congress call on the Department of Health and Human Services (HHS) Secretary to designate CCM services as "additional preventive services" available under Medicare Part B through its waiver authority outlined in Section 1115A(d)(1) of the Social Security Act in order to eliminate any beneficiary co-payment associated with CCM services. ACP believes that deeming CCM as an "additional preventive service" and thus removing the beneficiary co-payment will incentivize beneficiaries to receive these important CCM services.

Moreover, Section 1861(ddd)(2) of the Act requires the Secretary to use the process for making national coverage determinations (NCDs) when making any determinations under section 1861(ddd)(1) of the Act. The College recommends Congress encourage the Secretary to also waive this requirement to avoid creating unforeseen implementation problems or any further delay in beneficiaries with chronic conditions receiving appropriate care due to payment barriers.

### **Priority #6**

### **Short Description:**

Simplify and Align the Quality Measurement System to Ease the Burden of Reporting, Enhance Patient Care, and Build a Learning Health Care System

### **Summary:**

There is an opportunity provided within the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) legislation for the Centers for Medicare and Medicaid Services (CMS) to actively build a learning health and health care system that incorporates clinically relevant and accurate quality measurement. It is critically important that the new payment systems that are designed through the implementation of MACRA and the Quality Payment Program reflect the lessons from the current and past programs and also effectively allow for ongoing innovation and learning. Overall, quality measurement must move toward effective approaches of measuring clinically relevant care and patient outcomes. Additionally, as ACP noted in our comments to CMS on the draft Quality Measure Development Plan (MDP), it is important to constantly monitor the evolving quality measurement system to identify and mitigate any potential unintended consequences, such as increasing administrative burden and clinician burn-out, adversely impacting underserved populations and the clinicians that care for them, and diverting attention disproportionately toward the things being measured to the neglect of other critically important areas that cannot be directly measured (e.g., empathy, humanity).

#### **Related Statute/Regulation:**

Quality measurement sections of the 2018 Quality Payment Program Notice of Proposed Rulemaking

The College strongly recommends that Congress call on CMS to use ACP's Performance Measurement Committee (PMC) recommendations first when considering what measures to use for reporting by internal medicine specialists. ACP's PMC has reviewed and provided detailed recommendations on performance measures that are particularly applicable to internal medicine—and soon will have recommendations available for all internal medicine-relevant Merit-based Incentive Payment System (MIPS) measures. The PMC recommendations are based upon a scientific review process that involves four domains: purpose and importance to measure, clinical evidence base, measure specifications, and measure implementation and applicability.

Additionally, ACP recommends that Congress urge CMS to focus any additional performance measure proposals on the core sets of measures identified by the Core Quality Measures Collaborative and measures recommended by the Measure Application Partnership (MAP). Consistent implementation of these sets of quality measures will align and simplify the quality measure reporting process, reduce the burden associated with reporting, and most importantly focus on clinically relevant and accurate measures that improve quality and patient outcomes.

(See ACP's <u>Comment Letter to CMS Regarding MACRA/Quality Payment Program (QPP)</u>
<u>Proposed Rule for CY 2018</u> for additional recommendations)

### **Priority #7**

# **Short Description:**

Align varying policies, procedures, and contracting arrangements in the Medicare Advantage (MA) program with traditional Medicare to promote transparency and reduce excessive and burdensome administrative tasks.

#### **Summary:**

Medicare Advantage Organizations (MAOs) – as well as other private payers – have their own approaches and rules related to their business operations, billing requirements, prior authorizations, reporting of quality measures, referrals and treatment plans, and so on. These varying requirements across Medicare programs result in excessive administrative burden for participating physicians. For example, different Medicare Advantage (MA) plans may send guidance to participating physicians on certain services to provide to a patient based on the patient's specific MA plan and what the physician can bill for – even if that service is not entirely necessary at the time of the visit. These varying processes and guidelines make it difficult for a physician practice to manage and capture the appropriate charges (e.g., some MA contracts may allow physicians to bill for an Annual Wellness Visit [AWV] even though the patient received an AWV three months prior, whereas other MA plans allow an AWV to be billed 11 months apart, and others 365 days plus one day). Physicians should be clear on the intent of contracting arrangements and associated policies and procedures for participating in the MA plan so the appropriate and timely care of the beneficiary is at the forefront.

Additionally, aligning and streamlining the performance measurement system across Medicare programs and the commercial insurance market should be a priority in the efforts to decrease excessive and burdensome administrative tasks in the health care system. In addition to the complexities involved with contracting with multiple payers, navigating the differing data collection mechanisms and performance metrics systems across individual plans can become extremely time consuming and burdensome and take away from providing the high-quality care the metrics seek to capture.

### **Related Regulation:**

Updates to CMS policies made through the annual Medicare Advantage and Part D Rate Announcement and Call Letter

### **Proposed Solution:**

The College recommends that Congress call on Medicare Advantage Organizations (MAOs) to collaborate with one another and CMS to identify and analyze contracting arrangements and associated administrative tasks required for participation in their plans and either align varying arrangements and tasks, streamline duplicative tasks, or remove entirely tasks that are deemed excessive and burdensome using the comprehensive framework developed in ACP's position paper "Putting Patients First by Reducing Administrative Tasks in Health Care."

ACP believes the quality measurement systems for both Medicare Advantage plans and traditional Medicare should align in a way that promotes high-value care for all beneficiaries, streamlines quality reporting across Medicare programs, and promotes administrative simplification. A key approach in addressing the issues with the performance measurement system is for all stakeholders, including CMS, MA plans, other payers, electronic health record (EHR) vendors, and physicians, to collaborate in better utilizing existing and innovative health information technology (health IT) to seamlessly extract information from EHRs and address issues of burdensome data collection and performance measure reporting.

Additionally, the College urges Congress to call on the Medicare Payment Advisory Commission (MedPAC) to conduct research on the effects of excessive administrative tasks on physicians and beneficiaries specific to participation in MA plans as well as research on best practices to help reduce excessive and burdensome administrative tasks and further align administrative processes within the MA program and across traditional Medicare.

### **Priority #8**

### **Short Description:**

Promote Practical Interoperability/Specific Query Functions of Patient Information

### **Summary:**

The health information technology (health IT) industry has had numerous discussions concerning what is needed for practical interoperability. Specifically, what is actually needed to improve care and value without losing the patient's and clinician's narrative while avoiding information overload. It cannot be addressed until a fundamental level of electronic health

record (EHR) operability is universally available. Interoperability must serve the objective of better care and not be an endpoint in and of itself. True interoperability can only be assessed by measuring what it accomplishes, such as whether it improves quality and safety or reduces redundancy and duplicative administrative tasks. There is growing concern among physicians that the result of improving interoperability will be a flood of data that they will be responsible to read, manage, and to act upon. It is important to note that more data does not necessarily equal better care; and data without sufficient context may lead to diagnostic or treatment errors. For interoperability to serve the interests of patient, it should be developed and implemented iteratively, so that its effects on patient care are adequately demonstrated and the risks of data overload and data without context are mitigated.

### **Related Statute:**

There are several provisions included in the 21<sup>st</sup> Century Cures Act that directs the federal government to address interoperability and barriers to interoperability:

### Certification:

The law defines interoperability and expands the Office of the National Coordinator for Health IT (ONC) Certification program to include that health IT vendors be able to attest that their products: do not block information exchange; do not prohibit or restrict communication regarding usability, interoperability, security, user experience, business practices of developers, and how users use health IT; publish application programming interfaces (APIs) to allow for information exchange (including access to all data elements of a patient's EHR); have successfully demonstrated interoperability in its type of setting.

<u>Trusted Exchange Framework/Common Agreement for Health Information Exchange</u>:

ONC is also starting work on a provision that directs them to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally. Through notice and comment rulemaking, ONC will establish a process for health information networks that voluntarily elect to adopt the trusted exchange framework and common agreement to attest to such adoption in an effort to help move digital health information across the health care ecosystem.

### Information Blocking:

The law also defines information blocking and directs ONC to establish a standardized process for the public to submit reports on claims of health IT products or developers of such products not being interoperable or resulting in information blocking.

### **Proposed Solution:**

# **Common/Standardized Data Sets:**

As a step towards interoperability, there has been discussion around the definition of common data elements and sharing that standardized information seamlessly across the health care ecosystem. The Health IT Advisory Committee (HITAC) established through the 21<sup>st</sup> Century Cures law is instructed by the law to conduct an analysis of existing standards including an evaluation of the need for a core set of common data elements and associated value sets to

enhance the ability of certified health information technology to capture, use, and exchange structured electronic health information.

ACP believes that there is no clear path to a minimum data set that can cover all clinical use cases, or even the majority of clinical use cases, because such use cases are only now beginning to emerge, particularly for value-based care. Any attempt to define and mandate the use of a universal minimum data set would be naïve and could falsely lead policy makers to believe that a problem has been solved. First and foremost, the data collected must be accurate and consistent. This is clearly not the case today. ACP has provided ONC with an <u>analysis</u> of many of the current problems with current data collection practices that must be resolved before clinicians will be able to trust the data they see in patient records. Also, it is not simply the data elements that are important, but rather the management of these data along with the clinical context in which they were collected that are most critical. In many cases, knowing the source of a data element is critical to determining the level of trust that a clinician will place in the accuracy of the element.

Finally, it is essential that the narrative components of the record not be left off of any clinical data exchange. It is not possible to understand the patient's condition without including the patient's story. It is also essential that the clinician's reasoning about the patient be included in every information exchange. Therefore, ACP recommends that Congress urge ONC and the HITAC to focus their analysis on establishing a set of standard approaches, based on best practices, for consistently collecting and maintaining common data elements. We believe the focus on improving the accuracy and consistency of the data elements would be a better approach than mandating the use of a defined core set of data elements.

Trusted Exchange Framework/Common Agreement for Health Information Exchange

ACP recommends that Congress oversee ONC's implementation of the Trusted Exchange

Framework provisions of the 21<sup>st</sup> Century Cures Act to ensure that stakeholders can

voluntarily participate without ONC over-regulating certain requirements in a way that stifles innovation and further development of the exchange.

### **Information Blocking**

One barrier to interoperability is information blocking. While ACP strongly agrees with the goal of prohibiting information blocking, physicians and practices should be protected from being asked to absorb excessive costs associated with purchasing expensive EHR interfaces that have little clinical value. We are concerned that physicians could be accused of information blocking if they refuse to purchase and implement every data interface that their patient wants them to use. On the other hand, physicians are obligated to provide their patients with "all" of their data. Current EHR systems are not capable of exporting all of the data they contain about any given patient and they typically charge tens of thousands of dollars to export only a portion of the patient data contained in their systems. The College recommends, as Congress oversees the implementation of the 21<sup>st</sup> Century Cures Act, that they take into consideration the issues physicians face with information blocking that are out of their control and ensure that physicians are not held responsible for information blocking in those specific scenarios.

# Priority #9

### **Short Description:**

Reduce the Burden of Public Health Reporting

#### **Summary:**

As with the rise of the quality movement in hospitals in the early 1900s, the current shift from volume-based to value-based payment models is driving the need for more structured data. Electronic health record (EHR) systems lead to expectations of easier and more complete access to coded clinical information among non-clinicians who depend on clinical records to do their work. Entities that desire these data, such as public health entities, are adding more structured and coded data requirements to their reporting specifications in an effort to obtain more robust data sets.

Public health entities, such as state and local health departments, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Occupational Safety and Health Administration (OSHA), all have different forms and different structured data requirements for their reporting requests. This in turn places a burden on clinicians to submit information in a wide variety of forms and structured data that do not fit within clinical workflow patterns. The ideal scenario would be for clinicians to have the ability to extract necessary data automatically from patient records, compile the data into reports, and export them with the click of a button. This process, if it worked well, would be far more efficient and effective than the current process of manual chart abstraction; additional data entry at the point of care; and dependency on claims data for measurement of quality, public health reporting, research, and regulatory compliance. However, we are not at this point in EHR functionality, due to a variety of reasons including the lack of standard data elements in public health reporting.

Currently, as noted above, public health entities see the EHR as a way to collect their data directly from clinicians at drastically reduced costs versus alternative ways of obtaining these data as described above (i.e., data extraction). When they require data from practices and hospitals, each entity usually requires that the data elements be defined, structured, and formatted differently from the way the data are collected during the delivery of clinical care. This means that the reporting clinicians assume the burden, having to manipulate the data in ways that decrease the accuracy and value of the data elements. And those data requests vary among public health entities.

### **Related Statute/Regulation:**

The varying public health agency regulations and reporting requirements (e.g., Food and Drug Administration [FDA], the Centers for Disease Control and Prevention [CDC], and the Occupational Safety and Health Administration [OSHA])

### **Proposed Solution:**

Therefore, the College recommends that Congress call on public health entities to collaborate and develop a single format for all data reporting and collection by physicians and health care

**delivery organizations.** This format could be delivered through a single national portal/registry or local/regional entities such as health information exchanges (HIEs).

# Priority #10

### **Short Description:**

Promote a National Initiative that Uses a Common Set of Data Elements to Match a Patient to his/her Individual Electronic Health Information and Study the use of a Voluntary Universal Unique Healthcare Identifier

#### **Summary:**

ACP believes that patient identification and matching is a significant and growing problem as more health IT systems come online and begin attempting to exchange data, and as databases of patient records grow larger and larger – not only leading to privacy and safety concerns for patients but also adding to the burdens associated with using health IT. For nearly two decades, innovation and industry progress has been stalled due to a narrow interpretation of the language included in Labor, Health and Human Services, and Education appropriation bills since FY1999, prohibiting the Department of Health and Human Services (HHS) from adopting or implementing a unique patient identifier. The provision prohibited funds from being used "to promulgate or adopt any final standard...providing for...a unique health identifier for an individual...until legislation is enacted specifically approving the standard." That language was included in the House FY2018 Labor-HHS-Education appropriations bill.

# **Related Statute:**

The 21<sup>st</sup> Century Cures law directs the General Accountability Office (GAO) to review the policies and activities of the Office of the National Coordinator for Health IT (ONC) and other relevant stakeholders (which may include standard development organization (SDO) experts in the technical aspects of health information technology (health IT), health IT developers, providers of health services, health care suppliers, health care payers, health care quality organizations, states, health IT policy experts, and other appropriate entities) to:

- ensure appropriate patient matching to protect patient privacy and security with respect to electronic health records (EHRs) and the exchange of electronic health information;
- and survey ongoing efforts related to the policies and activities and the effectiveness of such efforts occurring in the private sector.

It also instructs the GAO to evaluate current methods used in certified EHRs for patient matching based on performance-related factors and determine whether ONC could improve patient matching by taking steps including defining additional data elements to assist in patient data matching; agreeing on a required minimum set of elements that need to be collected and exchanged; requiring EHRs to have the ability to make certain fields required and use specific standards; and other options recommended by the relevant stakeholders consulted.

Absent a National Patient Identifier, ACP supports a national initiative that explores the use of a common set of data elements to match a patient to his/her individual electronic health information. However, ACP is concerned that this may require the use of a relatively large set of identifiable patient demographic data to support matching. We believe this dependence on so many data elements may present a privacy risk for all patients.

Accordingly, ACP believes that use of a Voluntary Universal Unique Healthcare Identifier that patients could opt in to could provide privacy benefits and that its potential use should be studied. Accurate identification of patients and accurate association of patients with their data is a safety issue. What increased risk would this identifier present beyond the actual risks inherent in our current identification system? What benefits might it offer? A voluntary universal unique identifier for patients that has no other use beyond associating them with their health records might be less risky than using a set of demographic information that could have value beyond identification for health care purposes. We believe that this issue should not be dismissed without thorough evaluation of the potential risks and benefits. Therefore, the College strongly recommends that Congress call on the Secretary of HHS to initiate a thorough study of the risks and benefits of a voluntary universal unique patient identifier.

Also, ACP recommends congressional staff examine the work Integrating the Healthcare Enterprise (IHE) has been doing around patient identification. ACP is a sponsor of the IHE Patient Care Coordination (PCC) domain which was established in 2005 to deal with integration issues that cross providers, patient problems or time. It deals with general clinical care aspects such as document exchange, order processing, and coordination with other specialty domains. PCC also addresses workflows that are common to multiple specialty areas and the integration needs of specialty areas that do not have a separate domain within IHE. The IHE PCC Technical Committee will be releasing a white paper in the near future specifying patient demographic data elements that should be collected and exchanged for patient registration during an emergency visit at a health care organization. This may be a useful resource in the patient identification and data matching conversation.

### Priority #11

### **Short Description:**

Implement the Appropriate Use Criteria (AUC) without Imposing Undue Administrative Burden on Participating Physicians.

#### **Summary:**

The Centers for Medicare and Medicaid Services (CMS) are required by law to implement an Appropriate Use Criteria (AUC) Program for Advanced Diagnostic Imaging. Physicians ordering certain advanced diagnostic imaging will be required to use approved AUC through a qualified clinical decision support mechanism (CDSM) and provide information on what AUC and CDSM were used and whether the service that was ordered adhered to the AUC. ACP has general concerns regarding the AUC program as proposed, By implementing the AUC program as proposed, CMS is inserting a third-party between the doctor and the patient during the

diagnostic process. This will result in some level of delay, confusion, and concern among patients who may be justifiably anxious to determine the cause of their symptoms as well as adding unnecessary administrative burden for the ordering physician if the CDSM is not implemented properly.

# **Related Statue/Regulation:**

The Protecting Access to Medicare Act of 2014 (PAMA) requires CMS to establish a program to promote the use of appropriate use criteria (AUC) for clinicians who order advanced diagnostic imaging services through clinical decision support mechanisms (CDSMs). The CY 2018 Physician Fee Schedule Notice of Proposed Rulemaking solicits feedback on various implementation aspects of the AUC program including delaying the program start date from 2018 to beginning an educational and operational testing year in 2019.

# **Proposed Solution:**

Overall, the College supports CMS' proposed implementation delay. **ACP recommends that** Congress urge CMS to pilot test and evaluate the AUC program before moving to this complex and expensive system including:

- Review of whether the program leads to more appropriate use of advanced imaging and/or better or different billing code selection
- Collaboration with patient advocacy organizations to provide educational materials on the purpose and process behind the AUC program.

# The College also recommends that Congress call on CMS to:

- Decrease the administrative burden associated with participating in the AUC program by ensuring the CDSM is a proactive tool and implemented at the physician's point of decision making - not after the ordering physician has submitted the test
- Engage with other payers and encourage them to follow the same AUC criteria outlined by the Agency in order to align processes and lessen the administrative burden for participating physicians.

Thank you for considering ACP's comments. Please contact Richard Trachtman, Director, Legislative Affairs, by phone at 202-261-4538 or e-mail at <a href="mailto:rtrachtman@acponline.org">rtrachtman@acponline.org</a> if you have questions or need additional information.

Sincerely,

Jack Ende, MD, MACP

President