July 18, 2017

The Honorable Tom Price, MD
Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Price:

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 write to express concern with the substantial and unnecessary burdens imposed on physicians and their practices by certain existing regulations that negatively affect the delivery of care to patients covered under federal health insurance plans.

The ACS puts the welfare of our surgical patients above all else, and we support policies and regulations that improve patient care, reduce the administrative burdens placed on providers, and streamline workflow. Specifically, we ask the Department of Health and Human Services (HHS) to examine the following issues, which are further described in the attached table, and to consider our recommended actions for regulatory relief.

- **Global codes data collection**: Over the past seven months, the ACS has prioritized member education on this issue, but despite our best efforts there are still practitioners who do not understand this policy, provider software that has yet to be updated, and clearinghouses that have not tested and confirmed that they will be able to comply with the new data reporting requirements. CMS has not assured practitioners that all claims submitted with the required data will be captured and counted, shared a detailed plan for data validation, or provided transparency on how the data will be used in the future.

- **MIPS benchmarking**: MACRA requires that, starting in 2019, the MIPS performance threshold be set at the mean or median of the composite performance score, thereby penalizing approximately half of all Part B providers. Our concern with this policy is that the current CMS solutions to measurement science are not enough to accurately inform patients and providers.
- **Interoperability**: The clinical care model is growing increasingly complex with a vast amount of digital information that must interoperate, thereby creating a high demand for the exchange of digital health information. This information must also be synthesized and represented back to the provider in a convenient and usable format. Without access to interoperable and usable digital health information, providers spend hours documenting and searching for information which is extremely burdensome. The current digital environment cannot deliver the information needed by a surgical team to provide even basic care.

- **Prior authorization**: Some aspects of current prior authorization processes are inefficient and lacking in transparency, costing physicians and their practices money and time away from patient care. Lengthy and confusing prior authorization requirements often delay medically-necessary treatment, putting patients at risk for negative health outcomes.

- **Skilled nursing facility three-day stay requirement**: The three-day stay requirement compromises some patients’ access to necessary post-hospital care coverage under Medicare Part A and contributes to avoidable hospital admissions. This rule assigns an arbitrary timeframe to patient care and detracts from physicians’ clinical judgement in determining a patient’s status.

- **Program integrity**: Physicians are subjected to numerous pre-payment and post-payment reviews from CMS and its contractors, who often do not comply with requirements related to communication of physicians’ responsibilities and appeals rights during an audit. Many contractors receive incentives to conduct reviews more frequently, but are not penalized if these reviews are low-quality or inaccurate. Physicians are required to comply with contractors’ excessive requests for medical documentation and must bear the cost of producing the documents needed to satisfy audit requirements.

- **Two-midnight rule**: The two-midnight rule has not been successful in creating uniform criteria for inpatient status or in substantially reducing the number of long outpatient stays for Medicare beneficiaries. This policy assigns an arbitrary timeframe to patient care and detracts from physicians’ clinical judgement in determining a patient’s status.

- **Evaluation and Management documentation and electronic health records**: The Evaluation and Management documentation guidelines were developed in 1995, and revised in 1997, when medical records were paper-based. In the digital EHR era, these guidelines are antiquated and easily proliferated, creating voluminous medical records. The medical record has become a hindrance to care and communication among providers.
- **Documentation, certification, and recertification**: Medicare documentation policies set forth redundant requirements for verifying physician orders, delaying patient access to services and equipment. Physicians are required to provide an exorbitant amount of information to certify medical necessity and must navigate voluminous documents to validate CMS’ certification requests.

- **Medical translator services**: Physicians must provide verbal or written translation services at no cost to patients, but do not receive reimbursement for such services from CMS. The cost of retaining a qualified translator often exceeds the total Medicare payment received by a physician for the treatment provided.

- **Lack of support for evolving clinical care models**: While clinical care models have transitioned to team-based approaches to better address the needs of patients, many other aspects of care delivery have not similarly evolved. Efficient digital healthcare platforms, appropriate quality measures, and team-based business models can reduce burdens for physicians and improve collaboration among providers across episodes of care to more effectively treat patients longitudinally.

- **Transplant center certification requirements**: CMS and the Organ Procurement and Transplantation Network require organ transplant centers to meet process and outcome criteria; requirements across these two agencies differ significantly, leaving physicians confused about how to comply. These requirements utilize different review processes and timeframes, and impose outcome measures that are difficult for many physicians to meet.

The ACS appreciates the opportunity to comment on these important issues and looks forward to continuing dialogue with HHS on reducing regulatory burdens. If you have any questions about our comments, please contact Vinita Ollapally, Regulatory Affairs Manager, at vollapally@facs.org.

Sincerely,

[Signature]

David B. Hoyt, MD, FACS
Executive Director
### AREAS FOR REGULATORY RELIEF

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<th>Global Codes Data Collection</th>
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<td>For 10- and 90-day global surgical services furnished starting July 1, 2017, physicians who are part of groups with 10 or more practitioners and who live in one of nine specified states will be required to report one CPT code 99024 for each postoperative evaluation and management visit they provide within the global period. This is a mandatory reporting requirement intended to allow CMS to gather enough data on postoperative visits for the purpose of improving the accuracy of valuation of surgical services under the physician fee schedule starting in 2019.</td>
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In addition to the claims-based data collection, CMS also finalized a policy to conduct a survey of practitioners to gain information on post-operative activities to supplement the claims-based data collection described above. CMS has not finalized the design of the survey instrument, but intends to begin surveying in mid-2017.

This data collection is a burden that impacts only practitioners who provide global services. Additionally, CMS has failed to address numerous implementation issues or provide adequate time for provider education. Further, CMS has not shared a detailed plan for data validation that provides assurance that data submitted will be accurately processed and connected to correct index codes.

### Authority:

Section 1848(c)(8)(B) of the Social Security Act, which was added by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), §523(a)


### Recommendation(s):

- We ask that CMS delay the claims-based data collection until such time that CMS (1) addresses outstanding implementation issues; (2) tests the reporting and data collection process; and shares a detailed plan for data validation so that practitioners can confirm that submitted data were actually received and connected to the correct index code. CMS should not impose this burden on select specialties until the data reporting process has been tested and shown to be effective.
- Given outstanding questions about implementation of this data collection process, as well as uncertainty about the validity of data collected under the current requirements, we strongly urge the Agency to avoid using such data to revalue global services starting in 2019.
- We also have very little information regarding the survey of practitioners, the second component of global codes data collection. The ACS urges CMS to not move forward with the practitioner survey until the survey has been thoroughly vetted and the specialties to be surveyed have had an opportunity to review it and provide feedback.
Commentary/Examples:
Over the past seven months the ACS has prioritized member education on this issue, but despite our best efforts there are still practitioners who do not understand this policy, provider software that has yet to be updated, and clearinghouses that have not tested and confirmed that they will be able to comply with the new data reporting requirements. Our Fellows have also struggled with the requirement to submit post-operative visits to maintain/verify current payment for their work given costs for billing services that many surgeons employ. Some offices are reluctant to incur the cost when every expense is important to the survival of practice in certain geographical areas.

In addition, it has been difficult to educate our members and stress the importance of completing the practitioner survey given the lack of information and timing of the survey. To our knowledge, only one individual from a selection of specialty societies has been interviewed on the format of the survey, and ACS has not had sufficient opportunity to provide input on the content of the survey.

Even if CMS is able to collect useful data, it is inappropriate to assign values to some CPT codes using a methodology that is completely independent from the RUC process. The RUC recommends work values for CPT codes based on their relativity to other CPT codes and not based on a sum of component services (e.g. building block methodology), so attempting to assign values outside of this relative value scale for some, but not all, CPT codes would be improper. In addition, this process disproportionately impacts some specialties – both in terms of data collection burden and how the data will be used.

MIPS Benchmarking
Burden: MACRA requires that, starting in 2019, the MIPS performance threshold be set at the mean or median of the composite performance score, thereby penalizing approximately half of all Part B providers. Our concern with this policy is that the current CMS solutions to measurement science are not enough to accurately inform patients and providers. In fact, the current measure results misinform patients and providers because of a lack of reliable and valid information. One solution proposed by CMS is harmonization of measure definitions, but accurate measurement requires more than common definitions. This was demonstrated when ACS harmonized the ACS National Surgical Quality Improvement Program NSQIP surgical site infection (SSI) measure with the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) SSI measure when measuring in the same facilities. After harmonization, results showed that NSQIP participants had higher SSI rates compared to the CDC NHSN registry. Through further study, ACS found that this discrepancy was not because NSQIP participants had poorer surgical outcomes, instead, the discrepancy was due to the lack of rigor used to track patients and collect data for use in the NHSN registry when compared to NSQIP. The MIPS measurement systems needs rigor in common data aggregation, common data analytics, and

The Society for Thoracic Surgery (STS) National Database is an example of consistency across measurement because one data system exists for one operations, allowing for a single method for data aggregation, analytics, and reporting. If STS had multiple vendors collecting and analyzing data, results would not be as useful even after large expansive efforts. Another challenge is that MIPS measures lack meaning for surgeons and surgical patients—many MIPS measures are topped out and are “singleton” which does not give a comprehensive picture of care across an episode. We question whether or not HHS believes it is in the best interest of the program to award or penalize physicians in the program using inaccurate information.

**Authority:**

42 USC 1395w-4(q)(1)(6)(D)(i) as added by MACRA. Sec 101. (c)

**Recommendation(s):**

Our ask is that HHS work with us to find a solution to the current MIPS benchmarking challenges:

- Additional flexibility in the benchmarking policy. More time is required to test and implement a statistically valid, more meaningful, measure framework which follows care across an episode.
- We propose solutions which provide consistent reliable methods for data definitions, methods of aggregation and normalization and methods for reporting to the payer and the public.

**Commentary/Examples:**

Additional flexibility in the benchmarking policy. More time is required to test and implement a statistically valid, more meaningful, measure framework which follows the phases of care.

ACS is developing a comprehensive measure framework inclusive of high value process measures across an episode of care coupled with complementary patient reported outcome (PRO) and patient reported experience (PRE) measures to measure surgeons across the phases of surgical care in alignment with a patient’s clinical flow, including: preoperative preparation, perioperative final prep, intraoperative care, postoperative care and post discharge. Each of these phases involves key processes, critical care coordination to primary care physicians and anesthesia, as well as the technical side of surgical care that relates to safety, outcomes and avoidable harms. This framework, which broadly applies to surgical care for cross-cutting comparisons, was constructed to allow for more detailed, procedure-specific metrics to be added when necessary, and it fits well for use in an Advanced Alternative Payment Model.

We propose solutions which provide consistent reliable methods for data definitions, methods of aggregation and normalization and methods for reporting to the payer and the public.

We welcome working with HHS to address some of the issues outlined with the current set of circumstances in the MIPS program, such as identifying ways to normalize physician data for comparison in MIPS and how to best compare surgeons given the limitations.
**Interoperability**

**Burden:**
The clinical care model is growing increasingly complex with a vast amount of digital information that must interoperate, thereby creating a high demand for the exchange of digital health information. This information must also be synthesized and represented back to the provider in a convenient and usable format—this begins to illustrate the concept of interoperability.

Without access to interoperable and usable digital health information, providers spend hours documenting and searching for information, which is extremely burdensome and takes away from patient care. The current digital environment cannot deliver the information needed by the surgical team to provide even basic care. As we transition toward episode-based care with shared accountability, the need for digital information to flow between all members of a team will grow more complex, yet is critical to successful patient care. To support the transition of health care and give providers the tools they need, we must translate the Office of the National Coordinator for Health IT (ONC) Interoperability Roadmap into an operational plan.

**Authority:**
Roadmap authority – Section 106 of MACRA
ARRA H.R.1
(42 U.S.C. 201 et seq.)
(42 U.S.C. 1395a(b)(3))

**Recommendation(s):**
- The appropriate HHS agency should aid specialty medicine and other stakeholders in the process of creating clinical conceptual models 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 interoperability then needs to be translated into technical interoperability to allow for the digital exchange of information for a specific purpose.

- To enable digital health information interoperability across EHRs, mobile devices, registries and patient clouds, we propose that the appropriate HHS agency assume a leadership and convening role for interoperability. 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 expertise. The physician community, in collaboration with other stakeholders, would then select specific domains to create interoperable solutions, and those domains would lead to open source interoperable digital standards.

- The appropriate HHS agency should create EHR certification standards to require EHRs to be compliant with the described open source digital standards. This would greatly aid in data liquidity, which would eliminate data blocking, and enable patient cloud environments.
Commentary/Examples:
We believe the interoperable solutions are best characterized by understanding use cases, which can be divided into four general interoperability use case categories:

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 illustrate the vision of interoperability, the American College of Surgeons is currently working on a conceptual framework for cancer interoperability. However, without support from HHS leadership and resources to expedite this process, this level of interoperability will be very slowly developed—a national model for accelerating interoperable solutions is needed. It is critical to realize that we are not going to solve interoperability problems with the continued development of one-off inoperable and siloed EHR products.

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<td>Prior authorization is a process through which approval for coverage of a service must be obtained by a clinician before the service may be furnished to a patient. This process is implemented across a wide range of healthcare services, including surgical procedures, hospital admissions, and prescription drugs, and is increasingly used as an arbitrary standard to control costs rather than a standard for appropriate use to guide providers in making treatment decisions. The opacity and inefficiency of prior authorization requirements deprive patients of timely, quality services and divert physician time away from direct patient care. The clinical and administrative burdens imposed by prior authorization requirements on providers and their practices often delay or interrupt treatment and can lead to severe, life-threatening health outcomes.</td>
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<td>Many prior authorization rules are determined by state law.</td>
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<td>• The ACS believes that existing prior authorization processes are onerous and divert resources away from patient care. We urge CMS to require through rulemaking the automation of prior authorization requests and decisions through uniform electronic transaction portals for medical and pharmacy services under Medicare Advantage, Medicare Part D, and Exchange plans. We</td>
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also ask CMS to enforce Medicare Advantage, Medicare Part D, and Exchange compliance with prior authorization rules mandated under HIPAA and the National Council for Prescription Drug Programs.

- The ACS also requests that CMS outline where the Agency has the authority and does not have the authority to require the automation of prior authorization requests and compliance with prior authorization rules across all other health plans. It is crucial that prior authorization information be entered into electronic platforms that can be transferred between physicians, administrative staff, and health plans to streamline payor-provider communications and reduce the number of claims denied due to authorization mishaps.

- In order to ensure that patients have timely access to care, prior authorization decisions should be transmitted by a health plan to a provider through the appropriate electronic portal within 24 hours for urgent care and 48 hours for non-urgent care.

- We ask CMS to automate prior authorization decisions for services or supplies, including prescription drugs and DMEPOS, that are standard for a specific condition or have been approved previously as part of a patient’s care treatment plan.

- We also ask that CMS require payors to publish online and send to physicians the basic components that are required in all denial communications and decision-making, including: a specific explanation for the denial of coverage; realistic timelines for the filing of an appeal that account for the delay providers experience in receiving the denial letter; and access to an appeal process with clear instructions on how the process works.

- We request that CMS require payors to have physicians available outside the standard 9 to 5 work hours for peer-to-peer review of a denial. The current process of leaving a verbal message requesting a peer-to-peer review and having the payer call back while a provider is in the operating room or in clinic with patients results in a tag-team event and a delay to patient care.

- The ACS urges CMS to further restrict prior authorization requirements to complex cases or to clinicians whose ordering patterns differ substantially from other practitioners after adjusting for patient population. Such new requirements could reduce administrative costs to providers and ensure prompt delivery of care.

**Commentary/Examples:**

Prior authorization requirements are overused and applied to all physicians, regardless of their adherence to appropriate use of evidence-based clinical guidelines. A 2016 American Medical Association survey of 1,000 practitioners indicated that, on average, a medical practice completes 37 prior authorization requests per physician per week, taking providers and their staff 16 hours – the equivalent of two business days – to process.\(^2\) A number of physician offices are forced to employ full-time staff who exclusively process prior authorization requests, as the task of completing all prior authorization requirements, which often include lengthy phone calls and submission of voluminous medical records, is too tedious for physicians and other staff to perform while simultaneously interacting with patients. Many patients remain in the hospital while awaiting prior authorization for necessary services or supplies that would allow them to be discharged earlier, which puts them at risk for more complications. For example, a

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patient requiring a vacuum-assisted closure (VAC) dressing for wound care at home experienced a 3-day delay in their discharge from the hospital while awaiting prior authorization for the VAC. After no response from the patient’s insurer, the patient and admitting physician elected to discharge without the VAC. Several days post-discharge, the patient returned to the emergency room with infection in the wound and was readmitted to the hospital. During this readmission, and more than a week after the prior authorization request was submitted, the patient received the VAC and was discharged with the appropriate wound care supplies. The patient’s delayed discharge, emergency room visit, and readmission could have been avoided if health plans were required to respond to prior authorization requests in a timely manner.

There is little to no consistency across payors’ prior authorization programs, forcing providers to spend significant time learning to navigate each health plan’s request submission process, and the lack of transparency in each payor’s guidelines often leads to denials for requested services. Further, health plans often do not provide physicians with a specific reason for a denied claim or guidance on how to appeal the denial. Health plans also differ in their adherence to clinical guidelines and recommendations made by medical organizations and often deny coverage for standard procedures and tests that are necessary and appropriate. For example, pre-operative or surveillance imaging for cancer cases require physicians and administrative staff to spend hours coordinating with health plans to obtain approval for such tests, despite National Comprehensive Cancer Network guidelines that recommend patients with cancer undergo imaging tests frequently following their diagnosis. Prior authorization should be standardized across all payors and triggered automatically for routine treatments to reduce time spent conferring with health plans to determine coverage, which delays necessary treatment and can create complications for patients.

Skilled Nursing Facility Three-Day Stay Requirement

**Burden:**
The Medicare skilled nursing facility (SNF) benefit is for beneficiaries who require a short-term intensive stay in a SNF. Beneficiaries must have a prior inpatient hospital stay of at least three consecutive days in order to be eligible for Medicare Part A coverage of SNF care. The distinction between outpatient and inpatient hospital services does not improve the care a patient receives, and increases the risk of financial harm to patients that receive outpatient observation services for long periods of time without an inpatient hospital admission. If a beneficiary is not admitted to a hospital as an inpatient for at least three days, Medicare will deny Part A payment for stays at a SNF.

**Authority:**
Section 226(c)(1)(B) of the Social Security Act and the implementing regulations at 42 CFR 409.30(a)(2)

**Recommendation(s):**
- The ACS supports a system where patients are assured that their care and financial obligations will not be adversely affected simply because of their patient status (a sometimes arbitrary assignment designed only to determine whether Medicare Part A or Part B applies) and the length of their inpatient stay. We ask that CMS use its demonstration authority to determine if waiving
the three-day stay requirement would reduce Medicare costs and maintain the quality of care provided to beneficiaries.

- The ACS urges CMS in future rulemaking to rescind the three-day inpatient stay rule in favor of providers’ clinical judgement for determining a patient’s inpatient/observation status.

**Commentary/Examples:**
When the three-day inpatient stay requirement was enacted in 1965 to prevent overutilization of Medicare, three days represented the minimum time necessary for a patient to be admitted to a hospital, evaluated, and discharged with a care plan. Today, this process is typically completed between one and two days. Advancements in medicine have significantly improved the healthcare provided to Medicare beneficiaries, but coverage rules for post-acute care has not changed in concert with these advancements. The Medicare three-day stay inpatient rule extends the length of stay for patients who require short-term, post-acute care services and forces physicians to hospitalized patients unnecessarily, where they are exposed to disease and receive treatment that could have instead been initiated in a SNF. Further, patients who are transferred from a SNF to an emergency room for treatment are required to be admitted to the hospital for at least three days in order to re-qualify for coverage of SNF services. This rule contributes to high Medicare costs and substandard patient care attributable to avoidable or prolonged hospitalizations.

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<th><strong>Program Integrity</strong></th>
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<td>Physicians are facing an increasing amount of pre-payment and post-payment scrutiny from a variety of government entities and contractors including CMS, Medicare Administrative Contractors (MACs), Recovery Audit Contractors (RACs), Unified Program Integrity Contractors (UPICs), Quality Improvement Organizations (QIOs), Comprehensive Error Rate Testing (CERT) contractors, Supplemental Medical Review Contractors (SMRCs), and Risk Adjustment Data Validation (RADV) contractors. CMS does not provide sufficient oversight to contractors reviewing Medicare and Medicaid claims and does not monitor contractor compliance with requirements that they communicate to providers their responsibilities and rights during an audit.</td>
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<td>Pre- and post-payment reviews are often voluminous and not completed in a timely manner, which deprives physicians of reimbursement for extended periods of time. Providers are needlessly burdened with exorbitant requests for clinical documentation from contractors and compliance with these requests cost practices significant time and money. This particularly affects small practices that do not have the resources to meet the demands of multiple audits or continue to provide quality care while waiting for payments suspended during the review process.</td>
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<td>Additionally, many contractors are awarded based on contingency fee payment structures, which provides incentives to conduct reviews more frequently. However, there are no corresponding penalties for contractors whose reviews are low-quality or discrepant with a physician’s records of medical necessity.</td>
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3 Lipsitz, L. The 3-Night hospital stay and Medicare coverage for skilled nursing care. JAMA. 2013; 310(14).
Authority:
Social Security Act, §1874A
Social Security Act, §1893
Social Security Act, §1902(a)(42)
Social Security Act, §1936

Recommendation(s):
- The accuracy and consistency of Medicare and Medicaid audit processes are suboptimal and place unnecessary clinical and financial constraints on physicians and their practices. The ACS urges CMS to develop a standardized approach through which audit contractors notify providers of a review, request medical records, and, where applicable, inform providers of the specific reason why a claim is denied and clearly state a provider’s appeal rights.
- Given the vast number of reviews that physicians may be subjected to, CMS should clarify the function and authority of each reviewer and develop an online portal detailing the sampling and extrapolation methodologies that each reviewer employs.
- To ensure that contractors with contingency fee structures are not benefitting from reviews that contain inaccuracies or are overturned, we ask CMS to impose fines and penalties for those who make errors.
- Expenditures, such as printing and shipping fees, for providers who receive clinical documentation requests from auditors are high, and we urge CMS to require auditors to reimburse providers for the medical records submitted. Physicians who win on appeal of an audit should be reimbursed the full cost, including interest, of complying with the review process by the auditing entity.

Commentary/Examples:
The amount of reviews and types of contractors are confusing, add unwarranted physician burden and unnecessary costs, and disrupt and distract from delivering care. These audits are a great source of frustration and expense for the surgical community, and physicians need a single transparent, consistent, and fair review process to reduce administrative burden. Physicians undergoing audits continue to provide services to patients while awaiting payment for claims that may have been submitted several years ago; this process also delays payment for recently submitted claims, resulting in a loss of revenue and impeding practices’ ability to maintain clinical operations.

Some auditors, such as RACS, are paid on a contingency fee basis and retain a percentage of the amount they recover for CMS with little regard for the burden and accuracy of the reviews conducted. Hospitals and physicians bear the cost of the audits, denials, and appeals, regardless of their outcome. Fraud contractors should not receive incentives for inaccurately identifying improper payments and should be held liable for the claims they deny if they are overturned during the appeals process.
The implementation of the two-midnight rule, which was intended to reduce the number of short hospital inpatient stays and long outpatient stays, has resulted in negative consequences that burden physicians and Medicare beneficiaries. Under the policy, inpatient stays that do not extend across two midnights after the point of hospital admission are not considered medically-necessary, unless a physician determines, based on their clinical judgment, that an exception to the two-midnight rule is warranted. The two-midnight rule has not been successful in significantly reducing the number of long outpatient stays billed by hospitals to Medicare, resulting in higher costs and greater limitations for beneficiaries seeking SNF care following a stay as an outpatient under observation status. Hospitals continue to vary in their use of inpatient and outpatient stays and often receive more payment from CMS for short inpatient stays than for short outpatient stays, even if the stays are for similar conditions. The two-midnight rule detracts from physicians’ clinical judgment and uses an arbitrary timeframe, rather than evidence for medical necessity, as a determining factor for hospital inpatient admission. The Medicare Payment Advisory Commission (MedPAC) voted unanimously on a draft recommendation to withdraw this rule, as it detracts from admission criteria that depend upon clinical judgment.

**Authority:**
FY 2014 Inpatient Prospective Payment System final rule, 78 Fed. Reg. 50496 and other associated rules and notices

**Recommendation(s):**
- The ACS urges CMS to rescind the two-midnight rule in favor of physicians’ clinical judgement for determining a patient’s inpatient/observation status.

**Commentary/Examples:**
There is little consistency among insurers, hospitals, electronic health record platforms, and physicians on what qualifies a patient for inpatient admission, resulting in significant administrative cost to hospitals and hours of physician time spent determining which circumstances constitute inpatient care versus what care can be delivered safely under outpatient observation status. Hospitals interpret inpatient/observation status differently, and some will not allow a physician to admit a patient as inpatient unless the procedure the patient needs is included on CMS’ inpatient-only list. Rational physician judgement should be held paramount to any time-based benchmarks for hospital admission, and physicians should not be required to predict a patient’s length of stay based on their condition at the time of the decision to admit.

**E/M Documentation and Burden:**
Use of EHRs has complicated Evaluation and Management (E/M) code selection and amplified flaws in the current E/M guidelines

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Electronic Health Records

through the ease of entering new data elements and bringing forward old, potentially outdated and erroneous narrative into current records. This often results in voluminous EHRs with extraneous notes of little or no value, including errors, which make it difficult to find relevant information.

**Authority:**
1995 and 1997 Documentation Guidelines for E/M

**Recommendation(s):**
- We urge HHS to convene a group of physicians, including surgeon representatives, to revise E/M documentation guidelines for physicians to bring these guidelines into the modern era and make them more compatible with EHRs. CMS should require a complete review and modernization of E/M guidelines in order to reduce burden, remove redundancies, and align use with EHRs. Such new guidelines should promote efficiency in the medical records, help streamline patient care workflow, and support interoperability.
- It is critical that information can eventually be entered into data fields that can be transferred and that data are able to be added in a machine readable form.

**Commentary/Examples:**
The E/M documentation guidelines were developed in 1995 and updated in 1997 when medical records were primarily paper-based. At that point, these guidelines served CMS to create accountability to describe the level of E/M codes selected for the services billed. Selecting the correct E/M code requires knowledge of numerous criteria, complex rules, extensive chart documentation, and a high degree of clinical judgment. The translation of current E/M guidelines to EHR systems has created a hindrance to care and communication among providers.

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Documentation, Certification, and Recertification

**Burden:**
Medicare documentation policies create significant burden that delays patient care with redundant requirements for verifying physician orders and reviewing voluminous medical records where important patient information is difficult to identify within pages of irrelevant, formulaic language. CMS will only pay for covered services if physicians certify and recertify medically-necessary care and equipment that patients require, including hospital stays, wheelchairs, colostomy supplies, diabetic testing supplies, physical therapy, and home health and hospice services. These documentation requirements are repetitious and tedious and require physicians to review lengthy charts to confirm an order that they have already certified as medically necessary.

**Authority:**
Medicare General Information, Eligibility, and Entitlement, Chapter 4: Physician Certification and Recertification of Services
Recommendation(s):

- The ACS strongly urges HHS to standardize and streamline forms and eliminate requirements for providers to recertify patient conditions every year when the patient is diagnosed with a chronic illness. Authorization for certain types of medical supplies should also be standardized across suppliers so that providers are not required to recertify a patient’s need for such supplies each time the patient switches supply brands. Additionally, physicians should be allowed to authorize their clinical staff, such as nurse practitioners and physician assistants, to complete certification forms on their behalf.
- We ask that HHS take a more targeted approach to the enforcement of documentation and certification requirements that focuses on providers and suppliers who regularly do not meet these requirements.

Commentary/Examples:

Physicians are expected to provide an excessive amount of information to certify medical necessity, including a written prescription for a service or item with the appropriate ICD-10 code, copies of medical notes to prove a patient’s condition, and specification of the reason the service or item needs to be rendered. For many cases, a prescription and ICD-10 code should be sufficient in certifying the diagnoses, symptoms and procedures a patient received. All durable medical equipment, prosthetics, orthotics, supplies (DMEPOS), and home health orders must be signed by hand by a physician, and all DME prescriptions require an in-person visit within a specific period of time to affirm that the patient needs the equipment; for example, a face-to-face visit is required to certify that an amputee needs a new prosthesis or an adjustment to an existing prosthesis, even if the patient has been an amputee for a significant amount of time. Additionally, patients using diabetic testing supplies require a visit with a physician to obtain a new hand written prescription with the applicable ICD-10 code for those supplies at least once a year or anytime that the supply item or directions change. Even when standardized treatment is prescribed for common services that follow evidence-based protocols, documentation and certification requirements continue to apply.

The certification and recertification process is further complicated by the lack of uniformity among documents included in a patient’s care plan, which includes numerous pages of redundant and unorganized information that is often difficult for the referring physician to interpret. While CMS has mandated electronic records for most services, physicians are required to review and sign paper copies of patients’ records for DMEPOS certification. The paperwork for DMEPOS and home health is so onerous that many physician offices are forced to employ full-time staff who exclusively review and verify that the information provided for certification is accurate; there is no reasonable way for a physician to validate all certification requests while seeing patients. Many certification documents arrive well after an order is given or a change is requested in a patient’s care plan, providing little to no change for a physician to change a patient’s care, stop services, or verify that the order is indeed accurate and should be signed.

Medical Translator Services

Burden:

In implementing the nondiscrimination requirements under section 1557 of the Affordable Care Act, the Office of Civil Rights within HHS requires that all physicians and healthcare facilities receiving federal funds provide meaningful access to verbal or
written translation services for individuals with disabilities or limited English proficiency. These services must be offered free of charge and provided by a qualified interpreter who adheres to HIPAA standards and demonstrates proficiency in medical terminology. Patients cannot be required to provide their own translators and must give specific consent for an adult relative to provide interpretation. Qualified medical translators can cost physicians hundreds of dollars per patient visit, and physicians often still incur an interpreter fee if the patient cancels without advance notice. This is an unfair burden imposed upon physicians, especially those operating small practices.

**Authority:**
Patient Protection and Affordable Care Act: Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31375

**Recommendation(s):**
- Federal funding for medical translators is needed so that patients with disabilities or limited English proficiency do not lose access to care. The ACS requests that the cost of medical translator services be taken into account as part of the cost of care delivery and asks that CMS provide reimbursement for CPT T1013 (sign language or oral interpretive services, per 15 minutes).
- To further reduce these costs, we urge the HHS Office of Civil Rights to revise the definition of “qualified interpreter to an individual with limited English proficiency” to allow the use of an adult, such as a relative or friend, accompanying a patient with limited English proficiency to interpret or facilitate communication.

**Commentary/Examples:**
CMS does not pay for medical translators and places the responsibility on physicians and healthcare facilities to provide and fund translation services for their patients. Practices that have multilingual clinical staff often use those staff as interpreters when appropriate, but asking clinicians to provide translation services diverts their time away from other patients. Retaining interpreters that are fluent in the appropriate dialect and are familiar with medical terminology is expensive, particularly when interpreters impose a time minimum for their services or charge travel and cancellation fees. These costs are often greater than the payment received by the physician for the services provided.

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<th>Lack of Support for Evolving Clinical Care Models</th>
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<td>Healthcare delivery has become increasingly complex, necessitating team-based clinical care models to effectively address the needs of patients. Although clinical models have evolved, the digital healthcare information that physicians use, the way that care is measured, and the reimbursement/business models available to physicians and their teams have not caught up. This gap results in a burden on physicians as they attempt to run smooth practices in a way that is best for their patients.</td>
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Recommendation(s):
The ACS asks that CMS adopt the following recommendations for digital healthcare information, measurement, and business models:

- **Digital healthcare information:** CMS should support interoperability that tracks longitudinal patient care regardless of EHRs that their providers use.
  - Work through ONC and NIH to partner with HL7 and HSPC for creating machine readable solutions that interoperate national specialty registries, patient clouds, smartphones and EHRs.
  - Support open source clinical & HL7 standards through CEHRT to assure EHRs comply with the logic models, terminologies, value sets for standardized wire formats to allow data flows with the least amount of data blocking
  - Monitor EHRs for data blocking
  - Support clinical decision support tools that optimize care
  - Govern over the open source standards to create and update those as clinical care dictates.

- **Measurement:**
  - CMS should support episode-based models that allow for shared accountability for team-based care
  - CMS should support creation of high value process composite measures of key processes of care
  - CMS should support measures of patient reported outcomes
  - CMS should fund development of appropriateness of care measures

- **Business models:**
  - CMS should recognize that MIPS with FFS alone fails to keep pace with rising practice expenses and may also apply penalties to practices based on unreliable and invalid measurement science. The impact will be to push physicians into APMs.
  - CMS should support business models that incentivize and reward team-based, shared accountability in patient care such as the ACS-Brandeis Advanced APM model.
  - CMS should not restrict access to care through gatekeeper models when such models deny patients access to appropriate specialties. ACS prefers physicians provide key roles in the longitudinal care plan of a patient with each clinician owning their role in shared accountability.

Commentary/Examples:
Due to advances in medicine, today’s care models have become increasingly complex. Because of increases in diagnoses and treatment options, clinical care now involves teams caring for patients beyond just a limited interaction. Once a gatekeeper system
for fee-for-service, care has now become a series of coordinated roles that can extend for longer periods of time including the care before and after a procedure. Physicians’ roles within the team can also change depending on patient needs. The physician responsible for the patient has traditionally been the primary care physician, but today the lead could be the orthopedic surgeon, for example, instead.

As the clinical model has evolved into one that is more team-based and less siloed, other aspects of care delivery have not kept up. First, there is a need for digital healthcare information and eventually interoperability to facilitate the functioning of longitudinal patient care models. Second, measurement of quality and cost must similarly evolve to support creation of high value process measures and measures of patient reported outcomes. Third, new business models should be encouraged that are team-based and that allow for episode-based care. CMS should endorse these changes in order to recognize the new team-based care models often used in healthcare today.

The widespread use of electronic health records (EHRs) has transformed digital healthcare information. EHRs have created the ability for physicians to catalogue care and track it longitudinally. Currently, information is primarily limited to the EHR that was used for capturing the data, but efforts to connect across EHRs are accelerating. The digital healthcare ecosystem will eventually involve platforms or “clouds” that aggregate care for a patient from several EHRs. These clouds will be able to connect with other digital platforms such as smartphones, clinical registries, and other patient advocates, allowing for use in clinical decision support. Such digital healthcare information interoperability should be promoted in order to support newly evolving clinical care models.

Healthcare business models must also move beyond fee-for-service in order to sustain the changing clinical care models and increasing team-based care. A solution that recognizes and supports patient care that is team-based, patient-centered, and longitudinal is the use of APMs. As opposed to FFS, APMs share risk and accountability and are more closely aligned with the current team-based nature of the practice of medicine.

We support APMs that require grouping of claims in a manner that considers all costs associated with a patient’s episode of care and attributing a portion of those costs based upon a provider’s role in the specific episode for the specific patient. These episodes could consist of both Medicare Part A and Part B charges and could incorporate Part D spending if data become available. In such an “all cost” environment, clinicians would not wish to have all costs attributed to them that are not directly related to care provided for the specific condition being treated. To account for this, each episode would require an episode-specific set of definitions for the series of relevant services plausibly associated with the given treatment or condition. This approach is ideal for episode-based APMs and is used in the ACS- Brandeis Advanced APM proposal which was recommended by the Physician-focused Payment Model Technical Advisory Committee (PTAC) at their April meeting. We welcome the opportunity to speak with Secretary Price and staff about this model and the opportunities it presents for supporting care delivery.

Today’s healthcare clinical models have evolved to keep pace with advances in medicine. To support these advances, changes are
needed in the digital healthcare information that physicians use, the way that care is measured, and the reimbursement/business models available to physicians. The gap in the transformation of clinical models and the infrastructure needed for them to succeed results in a burden on physicians.

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<th>Transplant Center Certification Requirements</th>
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<td>Under current law, both CMS and the Organ Procurement and Transplantation Network (OPTN) impose process and quality outcome requirements on organ transplant centers. The CMS and OPTN requirements differ significantly, both in outcome measures and in methods of assuring transplant centers’ compliance with Medicare certification guidelines. Together, CMS and OPTN enforce 123 requirements for transplant centers, but only approximately 30% of these requirements are actually reviewed by the appropriate agency. The imposition of each agency’s requirements, which use different review processes and are based on different timetables, inflicts unnecessary clinical and administrative burdens on transplant centers.</td>
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**Authority:**
Social Security Act, § 1881(b)(1)
National Organ Transplant Act, § 372(b)(2)

**Recommendation(s):**
- The ACS asks that CMS work in conjunction with OPTN to eliminate conflicting or duplicative regulatory requirements for transplant centers.

**Commentary/Examples:**
Transplant centers are among the only provider types that are required to comply with both outcome requirements and comprehensive process requirements as a condition of participation in the Medicare Program. Since outcome requirements are often viewed as out-of-reach for many providers, Medicare certification requirements generally instead focus on compliance with processes thought to contribute to positive outcomes. However, transplant centers are evaluated on the basis of their outcomes and are reviewed under conflicting criteria by CMS and OPTN.