SUBMISSIONS TO THE COMMITTEE ON WAYS AND MEANS, SUBCOMMITTEE ON
HEALTH REGARDING STATUTORY AND REGULATORY BURDENS ON OPTIMIZED
EFFICIENCY AND PATIENT CARE

Name of Submitting Organization: American College of Surgeons

Statutory ___ Regulatory ✔️

Please use the below template as an example of a submission regarding statutory or regulatory concerns.

Short Description of Concern: Global Codes Data Collection

Summary: 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.

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.

Related Statute/Regulation: 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); CY 2017 Medicare Physician Fee Schedule, 81
Fed. Reg. 80209-80225

Proposed Solution:

- 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.

Short Description of Concern: MIPS Benchmarking

Summary: 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 reporting. The Society for Thoracic Surgery (STS) National Database is an example of consistency across measure because one data system exists for one operation, 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.

**Related Statute/Regulation:** 42 SC 1395w-4(q)(1)(6)(D)(i) as added by MACRA. Sec 101. (c)

**Proposed Solution:** 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.
- CMS must provide consistent reliable methods for data definitions, methods of aggregation and normalization and methods for reporting to payors and the public.

**Short Description of Concern:** Interoperability

**Summary:** 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 must 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.

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

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Proposed Solution:

- 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.

Short Description of Concern: Prior Authorization

Summary: 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.


Proposed Solution:

- 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 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 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 to 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.

Short Description of Concern: Skilled Nursing Facility Three-Day Stay Requirement

Summary: 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.

Related Statute/Regulation: Section 226(c)(1)(B) of the Social Security Act and the implementing regulations at 42 CFR 409.30(a)(2)

Proposed Solution:

- 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.

Short Description of Concern: Program Integrity

Summary: 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.

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.
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.

**Related Statute/Regulation:** Social Security Act, §1874A; Social Security Act, §1893; Social Security Act, §1902(a)(42); Social Security Act, §1936

**Proposed Solution:**
- 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.

**Short Description of Concern:** Two-Midnight Rule

**Summary:** 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.

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

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

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Short Description of Concern: E/M Documentation and Electronic Health Records

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

Related Statute/Regulation: 1995 and 1997 Documentation Guidelines for E/M

Proposed Solution:

- 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.

Short Description of Concern: Documentation, Certification, and Recertification

Summary: 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.

Related Statute/Regulation: Medicare General Information, Eligibility, and Entitlement, Chapter 4: Physician Certification and Recertification of Services

Proposed Solution:

- 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.

Short Description of Concern: Medical Translator Services

Summary: 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.


**Proposed Solution:**
- 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.

**Short Description of Concern:** Lack of Support for Evolving Clinical Care Models

**Summary:** 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.

**Related Statute/Regulation:** N/A

**Proposed Solution:** 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.

**Short Description of Concern:** Transplant Center Certification Requirements

**Summary:** 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.

**Related Statute/Regulation:** Social Security Act, § 1881(b)(1); National Organ Transplant Act, § 372(b)(2)

**Proposed Solution:** The ACS asks that CMS work in conjunction with OPTN to eliminate conflicting or duplicative regulatory requirements for transplant centers.