

August 12, 2019

The Honorable Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-8016

Submitted electronically via <https://www.federalregister.gov>

Subject: (CMS-6082-NC)

Request for Information; Reducing Administrative Burden to Put Patients Over Paperwork

Dear Administrator Verma,

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS) and those represented by the orthopaedic state and specialty societies who agreed to sign on, we appreciate the opportunity to provide comments on the request for information to reduce the administrative burden and put patients over paperwork, published on June 6, 2019. AAOS believes that it is of utmost importance to collaborate with the Centers for Medicare and Medicaid Services (CMS) on solutions to the growing burden of paperwork, time spent interacting with an Electronic Health Record (EHR) instead of a patient, and physician burnout resulting from such tasks.

Modification or streamlining of reporting requirements, documentation requirements, or processes to monitor compliance to CMS regulations

Minimizing Documentation Requirements by Simplifying Payment Amounts

The AAOS believes any guideline update must ensure appropriate valuation of work and decreased reporting burden. CMS has stated that it wishes to decrease the documentation burden of physicians. The modification of documentation to correctly reflect work is a worthwhile goal, but compensation must reflect the work being done. A proposal that inextricably links decreased burden with a reduction in provider reimbursement is unacceptable.

The Role of Medical Decision Making in Evaluation and Management

AAOS appreciates CMS' efforts to comprehensively apply the tenets of the Patients Over Paperwork initiative. The AAOS supports a history and physical exam with documentation

guidelines that exclude unnecessary data points and redundant information. Interim history and physical documentation for established patients should be focused and relevant. We believe that the history and physical, and Medical Decision Making (MDM) are both necessary components of Evaluation and Management (E/M). However, the point system for history and physical documentation remains time consuming despite the use of EHRs. Components of patient history are stored and remain available in the EHR; re-entering data serves no purpose. We also encourage CMS to support team-based care. Physician attestation should be enough to support the documentation requirement, thus allowing for non-physician staff to enter clinical information into the health record.

The AAOS maintains that the MDM component of E/M is exceedingly complicated. E/M should be based on intensity, complexity, and time. MDM should account for the complexity of the diagnoses discussed, regardless of whether treatment is required, complexity of the treatments discussed, and level of risk associated with the medical conditions and treatment options. Time alone does not sufficiently account for the intensity, complexity, or medical necessity of the visit, as intense or complex conversations do not necessarily take much time. Under current guidelines, a new patient with a straightforward problem, such as tendonitis, will have a higher level of service than an established patient discussing alternative options after failed treatment due to the limited history and physical that may be documented. New guidelines should address this inconsistency.

The AAOS questions whether the perceived burden reduction is entirely attainable. The minimum standard of Level 2 documentation requirements is a welcome change. However, one of our concerns involves the creation of disparate Medicare, commercial payer, and legal documentation requirements. Implementation of any new guidelines would require significant and time-consuming changes. The incorporation of the new add-on codes would require staff training and novel activities to defend against audits. Additionally, many EHR and institutional billing systems are currently programmed to code visits based on documentation elements.

CMS should work closely with medical specialty societies to ensure that the guidelines reflect levels of E/M services. It is critical that all providers be involved throughout the process. Of note, the AMA has convened a CPT/RUC E/M Workgroup to tackle this complicated issue. The AAOS has been actively participating in their proceedings. We expect that the recommendations of this workgroup will appropriately represent the interests of both proceduralists and non-proceduralists.

Aligning of Medicare, Medicaid and other payer coding, payment and documentation requirements, and processes

As the number of dually eligible Medicare and Medicaid beneficiaries continues to increase, the need for a uniform and streamlined documentation system grows ever more pressing.¹ Initiatives to meet the needs of this population, such as Medicare Advantage (MA) plans and Medicaid managed care plans, will soon be insufficient at their current growth rates. Since 2005, the

¹ Data Analysis Brief: Medicare-Medicaid Dual Enrollment from 2006 through 2015, Prepared by CMS Medicare-Medicaid Coordination Office December 2016

proportion of Medicare beneficiaries enrolled in MA plans has steadily increased from 13% to 35% in 2018.² Likewise, the proportion of Medicaid spending dedicated to managed care organizations has increased 15% from 2013 to 2016 and constitutes 43% of all Medicaid spending.³ Yet, dual eligibles are just 20% of the Medicare population and 15% of Medicaid participants.⁴ AAOS supports the goals of the CMS Financial Alignment Initiatives (FAI) as a method by which to bridge this gap in care and expand payment modalities. Specifically, we welcome CMS/CMMI's proposal for State-Specific Models which encourages the development of bundled payment models for dual eligibles.

Enabling of operational flexibility, feedback mechanisms, and data sharing that would enhance patient care, support the clinician-patient relationship, and facilitate individual preferences

Stark Law

While the Stark Law is structured to control the volume of referred services, it is a strict liability statute that leads to heavy penalties for unintentional and technical errors by physicians and their staff. Liability statutes, such as the Stark Law, do not encourage physicians to participate in coordinated care models. The Bundled Payments for Care Improvement Initiative (BPCI) and Comprehensive Care for Joint Replacement Model (CJR) model reveal weaknesses in current law. The costs of compliance and disclosures required can be prohibitive for small and medium-sized physician practices participating in these models. Physician referrals in Accountable Care Organizations (ACOs) are theoretically exempt from the Stark Law requirements through fraud and abuse waivers. There should be similar exceptions or protections to physicians participating in Alternative Payment Models (APMs). As AAOS and several of our partners have noted earlier in our comments to CMS and the US Congress, we would like to reemphasize the importance of protecting the in-office ancillary services exception.

Health Information Exchange Across Payers

Patients often switch between health plans, and information can be easily lost. By requiring electronic health information to be transferred across health plans, patients can attain a more robust and comprehensive understanding of their health across their lifetime. AAOS agrees with CMS that this proposal could also reduce the burden on providers by preventing unnecessary letters of medical necessity, inappropriate instances of step therapy, and repeated utilization reviews, risk screenings, and assessments.

Achieving and maintaining interoperable access as well as the exchange and use of electronic health information are critical to ensuring a well-functioning health care system. Health information exchanges (HIE) and health information networks (HIN) play an important role in

² A Dozen Facts About Medicare Advantage, Kaiser Family Foundation November 2018

³ Data Note: Medicaid Managed Care Growth and Implications of the Medicaid Expansion, Kaiser Family Foundation April 2017

⁴ Three New Opportunities to Test Innovative Models of Integrated Care for Individuals Dually Eligible for Medicaid and Medicare, Seema Verma, April 2019

facilitating the access, exchange, and use of electronic health information across disparate settings and systems.

Linking patient data from the EHR with qualified clinical data registries

Electronic Health Records

AAOS welcomes CMS' interest in utilizing existing federal mechanisms to promote interoperability within the health care system. Steps to accelerate truly interoperable EHR and health IT systems should also be taken. Interoperability should not focus simply on the electronic sending, receiving, finding, integrating, and use of data from outside sources. It must allow the exchange and use of information to be secure, useful, and valuable to the patient and the provider. Much of the current medical communication and documentation within an EHR is unstructured free-text (e.g. case summaries, operative report descriptions, and decision explanations, etc.), and provides some of the most vital information for patient care. The Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs (the Strategy) takes a step in the right direction by recommending additional data standards that make access, extraction, integration, and analysis of data easier and less costly for physicians and hospitals, however, much more needs to be done. Efforts to promote effective, interoperable measures of data exchange should ensure a focus on the value of qualitative data type (such as the ones mentioned above), not just quantitative measures. Interoperability can ensure duplicative tests are avoided, important historical information is accessed by physicians in real-time, and longitudinal tracking of a patients' condition and treatment can occur, which in turn will improve patient care and outcomes.

Cybersecurity Safe Harbors

AAOS believes that the EHR donation exception is a valuable and necessary allowance. Relatedly, the EHR safe harbor should be extended and made permanent beyond its current 2021 expiration date. As CMS has recognized, EHR adoption and use is a critical component of care delivery both inside and outside of the Medicare program. The law should find ways to promote greater EHR infrastructure which accounts for the fact that hospital investment in shared infrastructure could create a prohibited financial relationship under current regulations. Given the importance of EHRs to the success of the Quality Payment Program and to the future of healthcare both in federal and private programs, the overall EHR donation safe harbor should be broadened. We believe the safe harbor should be permanently expanded to include donations of other important technologies that protect patients and improve care, such as data analytics tools, as well as training on these technologies.

Medicare Claims Data

We appreciate CMS facilitating AAOS Registries' access to Medicare claims data which has made our data robust and viable for longitudinal analyses. Unless qualified clinical data registries (QCDRs) can validate their data with real-time Medicare and non-Medicare claims data, their findings exist in a virtual vacuum and are of little benefit. With validation, QCDRs can provide CMS with information that can both save lives and incur significant cost savings for the

Medicare program. AAOS urges CMS to ease QCDR access to real-time Medicare claims data in keeping with the intent of the Medicare and CHIP Reauthorization Act of 2015 (MACRA) statute.

Clinical Data Registries

AAOS regrets that clinical data registries, such as QCDRS or qualified registries (QRs), have not yet been identified as a useful tool or recommendation for reducing Health IT and EHR burden. Registries are unique in that they can longitudinally track patient care, quality and outcomes without additional burden on the front end for physicians. At the same time, they can highlight variations in care, provide feedback to physicians, and identify best practices based on real-world evidence (RWE) generated and analyzed on the back end. The Strategy specifically mentions that “physicians and hospitals commonly identified the current set of health IT measures to be excessively burdensome relative to the value they provide.” Registries can help address this issue.

In 2018, AAOS joined 20 other medical specialty societies in writing a letter to CMS Administrator Seema Verma urging HHS to “allow eligible clinicians utilizing a certified EHR to participate in a clinician-led QCDR to qualify them as fully achieving all points for the Promoting Interoperability category of the Quality Payment Program’s Merit Based Incentive Payment System.” This change will not only help reduce reporting burdens, improve Merit-based Incentive Program System (MIPS) performance, increase Certified EHR Technology (CEHRT) use, drive interoperability, and improve quality and outcomes, but it will also satisfy the recommendation listed in the Strategy to simplify the scoring model for the Promoting Interoperability performance category. AAOS encourages HHS to adopt this proposal.

New recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, and providers

The simplification of the Merit-based Incentive Payment System (MIPS) through technical changes to MACRA is essential to improving quality and reducing the reporting burden for physicians. The current system, with four distinct categories for MIPS reporting, leads to a disconnect between the physician-patient experience and the reporting requirements. An alternative to this would be re-centering the quality measures around specific conditions or episodes of care that are relevant to the patients and physicians in a given practice. To further integrate the practice experience and the MIPS reimbursement process, AAOS supports scoring based on multi-category measures. For example, by awarding bonus points at the composite score level instead of to the quality performance category. Other technical improvements to MACRA could include removal of the total cost of care mandate, and the latitude for CMS to create separate performance thresholds for urban and rural practices.

Improve the accessibility and presentation of CMS requirements for quality reporting, coverage, documentation, or prior-authorization

Prior Authorization

AAOS appreciates that the Strategy recognizes that the prior authorization system is challenging for clinicians, frustrating for patients, and increasingly burdensome. In 2017, AAOS joined more than 25 organizations to set forth a comprehensive list of 21 principles to reduce the burden of prior authorization requirements. One area described how “the use of standardized electronic prior authorization transactions saves patients, providers and utilization review entities significant time and resources and can speed up the care delivery process.” AAOS is glad to see that CMS supports automation of prior authorization processes for medical services and equipment through adoption of standardized templates, data elements, and electronic transactions between providers, suppliers, and payers. Proprietary health plan web-based portals do not represent efficient automation or true administrative simplification, since they require health care providers to manage unique logins/passwords for each plan and manually re-enter patient and clinical data into the portal.

Several of the principles are particularly salient as they relate to the aims of the Patients Over Paperwork initiative. They include the inclusion of updated formularies with prior authorization and step therapy requirements embedded in the EHR to reduce the frequency of prescription rejections when patients are already at the pharmacy; a minimum 45-day window of prior authorization validity to guarantee the presence of coverage over the time period necessary to receive care; standardized utilization review entity prior authorization review criteria; an alternative clinical quality measure that payers may recognize in lieu of prior authorization; and the exemption of providers that participate in a financial risk-sharing model from the prior authorization and step-therapy requirements for those services included in the plan’s benefits.

Clinical Documentation

Overall, AAOS greatly appreciates the CMS’ interest in reducing physician burden associated with clinical documentation. As mentioned in the Strategy, CMS took new steps in the CY 2019 Physician Fee Schedule (PFS) final rule to attempt to reduce documentation requirements for office visit E/M codes. AAOS commends CMS’ efforts to clarify current policy for history and exam of office and outpatient E/M visits so that unnecessary data and redundant information already present in the medical record does not need to be re-documented.

Additionally, AAOS applauds the recommendation to alleviate the administrative burden on physicians by reducing documentation requirements and advancing best practices. As we continue to focus on value-based care, increase our reliance on technology, and explore the utilization of team-based care, we must reevaluate our methods of documentation. Alternative Payment Model (APM) adoption has remained slow for a variety of reasons, including the lack of specialty-specific Advanced APMs and an inability to satisfy the Qualifying Participant (QP) threshold. Nevertheless, waiving onerous documentation requirements for purposes of testing or administering APMs could help facilitate faster adoption. CMS should also simplify reporting (such as shortening the reporting period to 90 days) and scoring under the Promoting Interoperability category of MIPS.

Address specific policies or requirements that are overly burdensome, not achievable, or cause unintended consequences in a rural setting

AAOS shares CMS' desire to ensure rural providers have the resources and tools necessary to provide quality care via groundbreaking new technologies and methods. Continued innovation through new technologies represents the best approach to expanding the health care workforce into underserved areas. AAOS also agrees with the contention that "non-rural healthcare provider participation may confer benefits upon affiliated rural healthcare providers," such as greater access to medical specialists.

As has been previously explained, the Rural Healthcare Program's funding is capped at \$400 million annually. The convergence of limited rural access to specialists, the overall challenges of rural healthcare (especially for seniors), and the aging population presents an even greater need to fund and utilize innovative new telehealth tools. As more and more federal programs create avenues for virtual participation (such as the Merit-based Incentive Payment Systems' new "virtual groups"), greater investment in the technological infrastructure to participate in these programs can also help increase quality patient care and reduce costs. While CMS has developed technical assistance opportunities and has finalized additional bonuses for rural providers, we urge CMS to develop special and minimal reporting requirements for rural participants. This effort would facilitate rural providers such that they are compared with a rural cohort and similarly sized practices. Minimizing reporting requirements and consideration of infrastructure, resource, and sociodemographic risk are also important.

Opioid Epidemic

The opioid epidemic and the importance of mechanisms like prescription drug monitoring programs (PDMPs) represent another area where telehealth can play a role in reducing the burdens rural patients and providers face. Investments as straightforward as expanding access to a high-speed data connection or the technology to send and receive encrypted patient health information can give providers important patient care tools. These kinds of health IT investments would enable providers to incorporate PDMP access more smoothly into their workflow. Also, considering the 2017 cyberattacks on the British National Health Service, giving providers the tools to protect their existing technology is even more important. Additionally, AAOS strongly believes that electronic prescribing of medications promotes patient safety and that it should be possible for a surgeon and pharmacist to see all prescriptions filled in all states by a single patient. The ability to access to this type of database would enable physicians to help reduce opioid use, misuse, and abuse.

Thank you for your time and consideration of the American Association of Orthopaedic Surgeons' suggestions. We greatly appreciate the opportunity to share our thoughts on improving the efficiency and quality of the health care system. AAOS appreciates CMS' commitment to its continued efforts to reduce the administrative burden of physicians. If you have any questions on our comments, please do not hesitate to contact William Shaffer, MD, AAOS Medical Director, by email at shaffer@aaos.org.

Sincerely,



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President, AAOS

cc: Joseph A. Bosco, III, First Vice-President, AAOS
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The following state and orthopaedic specialty societies agreed to sign on to this letter:

Alabama Orthopaedic Society
American Association of Hip and Knee Surgeons
American Orthopaedic Foot and Ankle Society
American Orthopaedic Society for Sports Medicine
American Shoulder and Elbow Surgeons
American Society for Surgery of the Hand
American Spinal Injury Association
Arizona Orthopaedic Society
Arkansas Orthopaedic Society
Arthroscopy Association of North America
California Orthopaedic Association
Cervical Spine Research Society
Connecticut Orthopaedic Society
Delaware Society of Orthopaedic Surgeons
Florida Orthopaedic Society
Georgia Orthopaedic Society
Illinois Association of Orthopaedic Surgeons
Iowa Orthopaedic Society
Kansas Orthopaedic Society
Limb Lengthening and Reconstruction Society
Maryland Orthopaedic Association
Massachusetts Orthopaedic Association
Michigan Orthopaedic Society
Minnesota Orthopaedic Society
Missouri State Orthopaedic Association

Montana Orthopedic Society
Musculoskeletal Infection Society
Musculoskeletal Tumor Society
Nevada Orthopaedic Society
New Jersey Orthopaedic Society
New York State Society of Orthopaedic Surgeons
North Dakota Orthopaedic Society
Ohio Orthopaedic Society
Oregon Association of Orthopaedic Surgeons
Orthopaedic Rehabilitation Association
Orthopaedic Research Society
Orthopaedic Trauma Association
Pediatric Orthopaedic Society of North America
Pennsylvania Orthopaedic Society
Ruth Jackson Orthopaedic Society
Scoliosis Research Society
Society of Military Orthopaedic Surgeons
South Carolina Orthopaedic Association
South Dakota State Orthopaedic Society
Tennessee Orthopaedic Society
Texas Orthopaedic Association
The Hip Society
The Knee Society
Utah State Orthopedic Society
Vermont Orthopaedic Society
Virginia Orthopaedic Society
Washington State Orthopaedic Association
West Virginia Orthopaedic Society
Wyoming Orthopaedic Society