



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

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October 27, 2017

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Planning and Evaluation
Strategic Planning Team
Attn: Strategic Plan Comments
200 Independence Avenue, SW
Room 415F
Washington, DC 20201

Dear Strategic Planning Team,

On behalf of over 18,000 board-certified orthopaedic surgeons represented by the American Association of Orthopaedic Surgeons (AAOS), we appreciate the opportunity to provide comments on the Department of Health and Human Services (HHS) Strategic Plan 2018-2022 draft released in September. AAOS shares the Department's desire to promote greater affordability and balance spending, strengthen healthcare quality and patient safety, and improve access and expand choices. In its pursuit of those goals, AAOS urges the Department to consider the following recommendations, which address the needs of our members and the mutual goal of delivering quality patient care.

Objective 1.1: Promote affordable health care, while balancing spending on premiums, deductibles, and out-of-pocket costs

Appropriate Setting of Care and Site Neutrality

The Department's goals include modifying payments to achieve greater site neutrality and facilitate appropriate settings of care at a lower cost. Toward this end, Centers for Medicare and Medicaid Services (CMS) must allow orthopaedic procedures such as TKA, TAR, and TSA to be performed in the outpatient setting, while keeping in mind that the surgeon should be the final decision maker of which patients are appropriate candidates. Additionally, clear site selection criteria should be developed based on evidence-based guidelines. We would also encourage the Department to build partnerships with organizations such as AAOS which have already invested in registries and in the development and implementation of outcome measures, including patient reported data for use in quality reporting.

Objective 1.2: Expand safe, high-quality healthcare options, and encourage innovation and competition

Public Healthcare Data and Real-World Evidence

Improving the use of public health and health care data to empower decision making and to promote the use of evidence-based guidelines is an important step in meeting the Department's 2018-2022 goals. As the Food and Drug Administration's (FDA) recent Final Guidance on the "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices" explained, registries (and particularly qualified clinical data registries) can play an important role in providing the critical real-world data for the development of evidence-based guidelines. Registries offer the opportunity to monitor adherence to current evidence-based guidelines while also offering real-world evidence that provides insight into patient populations, disease presentation, care patterns or care variability, as well as outcomes. At the same time, registries and qualified clinical data registries (QCDRs) continue to face challenges, including the difficulty in obtaining access to real-time Medicare claims data for quality improvement and patient safety purposes (as required under Section 105(b) of the Medicare Access and CHIP Reauthorization Act). Unless 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 produce significant cost savings for the Medicare program. In order to improve the use of public health and health care data to empower decision making, the Department would be best served by utilizing the resources of private sector partners like the registry community.

Incentivizing Planning, Coordination, and Management of Services

AAOS shares the Department's desire to improve outcomes for people with chronic conditions. As we have stated previously, we believe this would be best achieved by placing a surgeon as head, or co-head, of surgical episodes, which would greatly incentivize better planning, coordination, and management of services across the continuum of care. Surgeons are the only party in the total episode-of-care that are involved in all aspects of the patient's care. No other provider is as important to the final patient outcome as the operating surgeon. It is logical that all orthopaedic episodes treated be overseen by orthopaedic surgeons, rather than an acute care hospital facility. In addition, we believe the surgeon bears the most risk and, ultimately, is best able to discern the optimal means to improve quality and efficiency. We would again encourage CMS to create a mechanism for a surgeon or physician group to participate with a third party who manages the episode, payments, and "shared savings" distributions.

In addition to placing the surgeon at the head of an episode-of-care, current Stark law can present challenges to effective coordination and management of care. Recent value-based payment models (e.g. the BPCI and CJR models) that require coordinated care across settings have revealed weaknesses of the 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. A similar exception or protection should be made available to physicians participating in alternative payment models.

Encouraging Innovation and Competition

AAOS recommends that the Department's Office of the National Coordinator (ONC) consider new innovation pathways that can be studied by providers. An innovation pathway could introduce needed change in the current logjam of information. Focusing on the past will limit the advancement of electronic health record (EHR) technology and potentially handicap the advancement of patient care, data, and efficiencies. Providers should be rewarded for the use of technology that may advance patient care outside the current certification schema.

As HHS encourages innovation through leveraging technology, it should also consider that electronic medical reconciliation for transition of care is one of the most important advances in the use of EHRs. The deficit in many locations is that home health agencies, skilled nursing facilities, hospices, long-term care facilities, and others may or may not have electronic medical records. Often, if they do, the systems do not talk to each other due to the local system build. The systems are locally configured and not turnkey systems on the market.

As it has in the past, AAOS strongly supports the development of interoperability standards for all EHRs. We also support the development of appropriate standards for meaningful use of electronic health records by government agencies and private carriers which balance the needs of patients and their families, physicians and their staff, and regulators. Finally, we believe these standards should be collaboratively developed by physicians through their professional organizations in cooperation with government agencies. The process should emphasize the requirements for the highest level of quality patient care while recognizing the limits and clinical specialty focus of physicians who use the systems.

It is more critical than ever before that HHS support rapid communication and coordination between public health practitioners and clinicians to increase use of evidence-based prevention strategies to address risk factors. Physicians need to be able to access and integrate key pieces of

a patient's demographics and health history into their EHRs from other sources in order to provide more comprehensive care. AAOS encourages setting a standard that only allows stakeholders to participate in data exchange if they can meet minimum standards for data exchange and security.

Objective 1.3: Improve Americans' access to health care and expand choices of care and service options

Physician Owned Hospitals

Expanding choices of care is a necessary step to improving quality of care. As part of its strategy to do so, we would encourage the Department to take any opportunity it can to relieve the regulatory burden on physician owned hospitals. Physician owned hospitals provide independently-recognized better quality care than hospitals operated by non-physicians or appointing boards, and can help meet the growing demand for healthcare services in rural and underserved areas. Especially as rural hospital failures accelerate, physicians (or physician-led groups) should be allowed to purchase them outright or partner in a joint venture with the current management structure. Making this avenue available to physicians also represents another way to satisfy the Department's goal of incentivizing access to rural medical care while increasing quality care.

Preserving Access to Quality Specialty Care

The Department should work closely with medical specialty societies to ensure continued access to quality specialty care. Innovative models for delivering such care represent one approach the Department has taken to achieve this goal. However, HHS must be careful to avoid creating models that impede, delay, withhold, or deny access to necessary specialty care. Many more of HHS's ongoing programs and endeavors also rely upon patient access to specialty physicians. As the practice of medicine has become increasingly specialized, it is important to ensure that patients have access to timely, high quality, affordable specialty care, including the physician of their choice.

Objective 1.4: Strengthen and expand the healthcare workforce to meet America's diverse needs

Encouraging Providers to Work in Underserved and Rural Areas

Physicians working in underserved and rural settings face unique challenges and burdens. AAOS applauds the Department for the steps it has already taken to incentivize these practices. However, there are additional actions that can be taken to further this objective.

AAOS appreciates the Department’s innovative proposal to permit small and solo practices to participate in the Merit-based Incentive Payment System (MIPS) via “virtual groups.” Although such a proposal leaves unresolved questions about the burdens of participation, we believe continued innovation through new technologies represents the best approach to expanding the healthcare workforce into underserved areas. Additionally, the proposed financial investments in education and technical assistance of small and solo practices and those in rural areas, under the 2018 Updates to the Quality Payment Program, represent another best practice for encouraging the Department’s sought-after workforce expansion.

In the meantime, there remain burdensome requirements under current law (e.g. the Affordable Care Act’s requirement for insurers and the healthcare industry to provide translation and interpreting services for limited English proficiency individuals). It can be more difficult to comply with certain requirements in rural areas than it is in more urban settings. We would encourage the Department to consider the different implications of requirements such as these as it tries to incentivize physicians to expand into rural and underserved areas.

Objective 2.3: Reduce the impact of mental and substance use disorders through prevention, early intervention, treatment, and recovery support

Reduce the Impact of Substance Abuse Disorders

The Department’s application of a public health approach for preventing opioid misuse, opioid use disorder, and opioid overdose deaths is commendable. In order to achieve this, we believe a comprehensive opioid program is necessary. Orthopaedic conditions naturally require narcotic pain management for weeks or months, particularly those involving trauma or aggressive post-surgical physical therapy. We understand the interest in prescriber education and training as part of the solution to this epidemic, and we would welcome voluntary physician programs toward this shared goal. New education programs on safe use, improvements in current programs for monitoring prescription drug use, increased research funding for effective alternative pain management, and support for more effective opioid abuse treatment programs can each play a role in reducing the impact of these disorders.

Thank you for your time and consideration of the American Association of Orthopaedic Surgeons’ suggestions to reform, strengthen, and modernize the nation’s healthcare system. 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,

A handwritten signature in black ink, appearing to read "Wilford K. Gibson". The signature is written in a cursive style with some loops and flourishes.

Wilford K. Gibson, MD

Chair, Council on Advocacy, American Association of Orthopaedic Surgeons

cc: Thomas E. Arend, Jr., Esq., CAE, AAOS Chief Executive Officer
William O. Shaffer, MD, AAOS Medical Director
Graham Newson, AAOS Director of the Office of Government Relations