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May 26, 2011

Donald M. Berwick, MD, MPP
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1345-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Section 3022 of the Affordable Care Act

Dear Administrator Berwick:

The American Association of Orthopaedic Surgeons (the "AAOS") appreciates the opportunity to comment on Section 3022 of the Affordable Care Act (hereinafter referred to as the "ACA" or the "Act"), which contains provisions relating to Medicare payments to providers of services and suppliers participating in Accountable Care Organizations ("ACO"). We represent over 18,000 board-certified, orthopaedic surgeons and have been a committed partner in patient safety, cultural competency, and providing high quality, affordable musculoskeletal care. We commend the Centers for Medicare and Medicaid Services ("CMS") in its efforts to develop payment and service delivery models to reduce program expenditures while enhancing the quality of care.

The AAOS believes that better coordination and integration of health care services can improve quality of care and patient satisfaction. The AAOS currently develops clinical practice guidelines, appropriate use criteria, and technology assessments; we initiated and are a partner in the American Joint Replacement Registry ("AJRR"); and we have published a primer to help educate orthopaedic surgeons on issues related to ACOs.

Governance and Legal Structure of an ACO

1. Governance

As proposed, the AAOS supports a governance mechanism that allows for appropriate and proportionate control, giving each ACO participant, including orthopaedic surgeons, a voice in the governance structure and decision making process. One of the biggest challenges in establishing an ACO is ensuring that solo practitioners, small groups, and small hospitals have the

option to participate. Over 20 percent of orthopaedic surgeons are in solo practice and as such the AAOS is acutely aware of how important the participation of solo practitioners and small hospitals will be. Presently, it appears the two primary pathways for solo and small practices to become a part of an ACO would be either to join a network [Independent Physician Associations ("IPAs")] or become hospital employees. To ensure that ACOs remain "provider-driven", CMS proposed to provide an opportunity for small provider groups to participate in the shared savings program as long as the governing body is controlled by 75 percent of the defined ACO participants. The AAOS supports CMS' efforts in providing this opportunity for small groups of providers who lack both the capital and infrastructure necessary to form an ACO and to administer the programmatic requirements of the shared savings program.

With the above noted, the AAOS is concerned that the failure to include appropriate anti-kickback waivers that would otherwise allow hospitals and larger, more well capitalized entities to contribute start-up costs to providers, may limit the number of small or solo practitioners participating in ACOs. This would be unfortunate, as it is important for all types of practices to be given access to vehicles and incentives to organize ACOs in order to improve quality and reduce costs. As such, we would encourage the CMS to strengthen this part of the regulations.

2. Legal Entity

The AAOS appreciates CMS' efforts to balance the need for flexibility to permit participants to select the appropriate organizational structure and consider the importance of minimizing costs related to organizing as a specific legal entity. The AAOS believes that as long as an existing legal entity meets the eligibility requirements to be a participating ACO as described in the proposed regulations, they should not additionally be required to establish a separate legal entity, in order to joint venture with other ACO providers. An additional entity would be duplicative in function and expense. As such, the AAOS urges CMS to reconsider this requirement.

Assignment of Medicare Beneficiaries

Section 1899(c) of the Act requires the Secretary to assign beneficiaries retrospectively to an ACO based on their previous utilization of primary care services provided by a physician. For the purposes of defining primary care services, CMS has proposed the option of assigning beneficiaries based upon both a predefined set of primary care services and a predefined group of primary care providers. The AAOS is concerned that this option may not adequately account for services delivered by specialists. It could reduce the number of beneficiaries assigned to an ACO, by excluding services delivered by specialists, especially in some areas that may have shortages of primary care physicians, but a relatively greater number of specialists. We would recommend the CMS

define primary care services by CPT code, and not by self-designated specialty. We share the CMS concern that doing so may limit the number of ACOs that a specialist can join, but we believe it is more important to ensure the correct inclusion of Medicare beneficiaries

The AAOS believes it is important for patients to have a freedom of choice and be encouraged to voluntarily choose the physicians who provide and coordinate their care. However, for Medicare beneficiaries who opt out of the ACO once they have been notified of their physician's participation, the ACO should not be penalized for patient behavior and preference. This would only discourage participation by smaller ACOs.

The AAOS is pleased CMS proposed some flexibility in handling ACOs that fall below the 5,000 beneficiary threshold during the participation period by issuing a warning and placing the ACO on a corrective action plan rather than uniformly dropping the ACO from the shared savings program.

As CMS has proposed that beneficiary assignments be done retrospectively to reflect actual beneficiary behavior in a given measurement year, the AAOS suggests that the ACO remain eligible to share in savings for the first and second performance year. If the ACO's assigned population has not returned to at least 5,000 by the beginning of the third performance year, then that ACO's agreement should be terminated and the ACO would not be eligible to share in savings for the second performance year. We also ask for further clarification on the type of corrective plan that would be implemented and how CMS would assist the ACO in adding more primary care providers, which should result in adding more beneficiaries to the ACO.

Quality and Measure Reporting Requirements

1. Health Information Technology

Fundamental to the success of all ACOs is a robust *Health Information Technology* ("HIT") platform. Unfortunately, the cost of HIT is so significant that it creates a substantial barrier to physician ACOs. As such, the AAOS urges CMS to create additional processes that facilitate physicians' acquisition of HIT. If this is not done, the health care system by default will ultimately be dominated by large, well capitalized entities with the concomitant loss of physician input and ingenuity.

2. Quality Metrics

Quality metrics related to musculoskeletal care are poorly defined as orthopaedics lacks adequate objective data to define quality outcomes from a patient perspective; and tracking and evaluating patient outcomes in terms of reduction in pain and improvement

in function and quality of life is difficult and expensive.[1] As described in the proposed regulations, 65 quality measures were identified to assess the quality of care delivered by an ACO. The measures span five domains: 1) patient/caregiver experience of care; 2) care coordination; 3) patient safety; 4) preventive health; and 5) at-risk population/frail elderly health. These measures are aligned with measures in other reporting programs such as the Electronic Health Records (EHR)/Meaningful Use and Physician Quality Reporting System (PQRS) Incentive Programs. However, the AAOS is concerned about the uncertainty of providers committing to a risk model that allows additional metrics or metrics to change within the three year period without recourse.

The AAOS is also concerned that there is a lack of alignment between the implementation and reporting requirements of EHR and PQRS programs. We encourage CMS to address how these measures will be aligned to prevent duplicative reporting and whether there will be a minimum number of measures per ACO participant required for reporting. We also would encourage CMS to provide mechanisms for ACOs to amend or add quality measures that suit their particular set of ACO participants. This type of flexibility would allow ACOs greater accountability and also make it easier for ACOs to develop specialty specific quality measures. The latter is particularly important because a vast majority of the 65 quality measures listed in the proposed rule are specific to primary care and not to specialty care. Having the quality measures so heavily tilted toward primary care measurements means that specialists in an ACO would have much less data as to whether the ACO meets the quality standards for specialty care. This could either inappropriately reward or punish specialist providers.

3. Appropriate Use Criteria

In order for primary care physicians and specialists to work together to provide high value health care while lowering costs and reducing duplicative procedures, CMS should consider incorporating appropriate use criteria into the quality measurements for ACOs. The AAOS believes that defining appropriate use of specialty care, including referral to specialists and diagnostic and therapeutic interventions, would help provide the basis for measuring quality within a shared savings model.

ACO Payment Models

The AAOS supports payment methodologies that will create incentives for coordination of care among providers (including physicians and hospitals). We commend CMS for proposing alternative payment models designed to accommodate the varying compositions of ACOs. Since it is impossible to develop a "one-size-fits all" model, it is

[1] Accountable Care Organizations: A Primer for Orthopaedic Surgeons. The American Academy of Orthopaedic Surgeons. (February 2011).

important that the models emphasize flexibility and be attractive to all levels of ACOs, including entities with limited organizational capacities; entities with some infrastructure or care coordination capability and demonstrated track record; and entities with a robust infrastructure, demonstrated track record in finances and quality and providing relatively full range of services. The AAOS believes that the one-sided and two-sided models offer this flexibility. That noted, the AAOS is concerned that the percentage of shared savings proposed by CMS (60% under the "two sided" model, 50% under the "one sided" model is not a sufficient incentive for the formation of, and participation in, ACOs, especially given the anticipated start-up costs (estimated to be over $1.7 million) and the three (3) year term of the agreement. We recommend to CMS that the one-sided model not be phased out in year 3 of the 3-year contract term, but rather allow ACOs that choose the one-sided model the option to either maintain or switch to the two-sided model. In all events, the percentage shared in the one-sided model should be increased in the year in which the risk of loss begins.

In addition, we believe the 60% figure is too low for the two-sided model where the ACO assumes a percentage of responsibility for expenditures above the target expenditure rate and assumes risk even within the first year. We would recommend a higher percentage for ACOs that choose to accept financial responsibility for costs above the target expenditure rate. By raising the total percentage of savings eligible for sharing above 60%, CMS could provide a sufficient incentive to ACOs to choose to transition to a two-sided model and accept more risk while also allowing ACOs uncomfortable with that level of risk to initially participate in the program. The May 17, 2011 "Pioneer" pilot project announced by the Centers for Medicare and Medicaid Innovation (CMMI) proposes to offer greater potential revenues for ACOs. However, the Pioneer project would be limited to entities that already have all the definitions of an ACO. We would encourage the CMS and the CMMI to extend this concept to start-up ACOs as well.

The AAOS agrees with CMS that reinsurance could be a mechanism to protect ACOs in the two-sided model against losses and we believe it is essential to provide a proper balance of risk to reward. However, we would encourage CMS in the final regulations to provide a clearer mechanism for ACOs to obtain reinsurance including possibly sponsoring reinsurance pools for ACO providers. There should also be recognition that bearing this kind of risk may subject the ACO to additional regulation and expense through various state insurance statutes.

We would also recommend that in the final rule the CMS clearly define the timetable for distribution of shared savings and also to provide a transparent appeal system. Many providers experienced significant delays in obtaining incentive payments through CMS programs like PQRS and were faced with an opaque appeals process. Given the importance and the high level of interest in ACOs, we would recommend CMS find a way to clearly define these issues in advance of any ACO beginning operations.

We also believe specialists should be allowed to develop payment distribution contracts within an ACO that support improved patient-level outcomes and cost reductions achieved by specialists. The costs to establish an ACO may negatively affect groups that are unable to provide sufficient capital or fund a proportionate share of their interest in the ACO. Furthermore, incentive payments from the shared savings program may take more than a year to generate. The AAOS encourages CMS to allow ACOs to participate in shared savings programs with commercial payers to provide cash flow to fund operations until Medicare shared savings payments become available and/or develop an infrastructure that allows the hospital-member of the ACO to fund a disproportionate amount of initial capital needs of the ACO such as the Advance Payment initiative program announced on May 17, 2011 by the Center for Medicare and Medicaid Initiatives. We would encourage CMS and CMMI to continue to explore and initiate programs like this to provide greater incentive for ACO participation.

Specialist Participation in ACOs

The AAOS would like to take this opportunity to provide input on the role of specialists in ACOs. Although we agree with and support the substantial role of primary care providers in coordinating care, we believe it is also important for CMS to consider various models for specialist participation in ACOs. Specialist physicians can and should play a vital role in ensuring the appropriate access to and use of specialty services by patients and their primary care providers. This could include such important tasks as defining appropriate use criteria for referral to specialists, advanced diagnostic imaging and other pre-referral testing, appropriate indications for therapeutic procedures, innovative solutions to enhance communication between primary care providers and specialist physicians, and clinically relevant performance measures related to specialty care. The AAOS shares CMS' vision of a fully networked, integrated health system where specialists and primary care physicians can fluidly share information and coordinate care because incentives are aligned. The AAOS welcomes the opportunity to work with CMS to better define the role of specialists in ACOs and shared savings program going forward.

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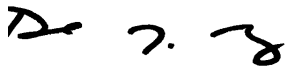
Again, we thank you for the opportunity to comment. Should you require any additional feedback from our surgical and specialty perspective, please do not hesitate to contact our Medical Director, William R. Martin, III, MD at (202) 546-4430 or martin@aaos.org.

Sincerely,



Daniel J. Berry, MD
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