



American College of Surgeons

Washington Office: 20 F Street, NW Suite 1000 • Washington, DC 20001 • 202-337-2701 • FAX 202-337-4271
e-mail: postmaster@facs.org ACS website: www.facs.org

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June 3, 2011

Donald M. Berwick, MD, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1345-NCS
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Daniel R. Levinson, JD, LLM
Inspector General
Office of the Inspector General
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Medicare Program; Waiver Designs in Connection With the Medicare Shared Savings Program and the Innovation Center; Notice with comment period

Dear Administrator Berwick and Mr. Levinson:

On behalf of the more than 75,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments on the proposal put forth on *Waiver Designs in Connection With the Medicare Shared Savings Program and the Innovation Center*. The 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. The ACS has a strong interest in the development of delivery and payment models that will help surgeons improve the quality of the care delivered to Medicare patients. As we collaborate to improve the delivery of health care, the ACS has embarked on a process of educating our members about the upcoming projects related to accountable care organizations (ACOs) and the Medicare Shared Savings Program (SSP). We submit these comments with the intention of improving the SSP and removing barriers to participation so that patients will receive improved care and have access to the full range of services necessary for quality of care. Our comments are presented in the order in which the relevant issues appear in the Notice with Comment Period and are intended to complement the separate set of comments we submitted in response to the Medicare Shared Savings Program notice of proposed rulemaking.

Chicago Headquarters: 633 N Saint Clair St • Chicago, IL 60611-3211 • 312-202-5000 • FAX 312-202-5001

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Administrator Berwick and Mr. Levinson

June 3, 2011

Page 2

MEDICARE SHARED SAVINGS PROGRAM: PROPOSED WAIVERS

Scope of the Proposed Waivers

As articulated in the comment letter we submitted in response to the *Medicare Shared Savings Program: Accountable Care Organizations* proposed rule, the ACS is concerned that the current proposals for ACOs and the SSP do not create the appropriate opportunity or incentives for participation by surgeons; participation that we believe is necessary to create true coordination of care across all health care services that patients will need within an ACO. We have provided suggestions that we believe will help increase participation by surgeons. However, in the interim we believe that it is also necessary for CMS and the Office of the Inspector General (OIG) to ensure that patients are able to receive necessary care and to provide opportunities to coordinate care of patients that are in an ACO regardless of whether a surgeon has been able to officially become part of an ACO. It is for this reason that we commend CMS and the OIG for addressing financial relationships that are created by a distribution of shared savings *outside* of an ACO when those distributions still closely resemble other ACO requirements and goals. For patient protection and program integrity purposes, we understand the need for the protection of the distribution to a non-ACO provider to be “for activities necessary for and directly related to the ACO’s participation in and operations under the Medicare Shared Savings Program.” We believe that including these relationships is an important piece to ensuring that patients have access to necessary care while we all work to improve the ACO regulations to provide the opportunity for broader participation.

Because of our concerns about the complexity of creating ACO arrangements, potential barriers to participation, and the desire to launch these arrangements with the hope of providing better care for patients, we also commend CMS and the OIG for coordinating the protections under the Physician Self-Referral Law and the Anti-Kickback Statute. The decision to depart from past practice and allow the Anti-Kickback Statute waiver to apply to arrangements that fit within a Physician Self Referral exception appropriately balances the necessary safeguards with the need to create an environment in which the creation of ACOs can succeed. We agree that this is an appropriate action to take to minimize burdens on entities establishing ACOs.

One area in which we have concern is the discussion of the “Prohibition on Hospital Payments to Physicians To Induce Reduction or Limitation of Services (Sections 1128A(b)(1) and (2) of the Act)” or the Civil Monetary Penalty (CMP). It is our firm belief that the governance structure of ACOs must provide for fair representation of all stakeholders. In addition, in the current discussion of waiver design, CMS and the OIG have proposed protections primarily for the distribution of shared savings. The CMP is designed to address payments from *hospitals* to physicians. It is unclear how, under a properly structured ACO, shared savings would flow from a hospital to



Administrator Berwick and Mr. Levinson

June 3, 2011

Page 3

physicians. The shared savings distributions should only be made *by* an ACO (with a proper governance structure) *to* the physicians (and participating hospitals). We firmly believe that a properly designed ACO governance board should not be synonymous with a participating hospital. We request clarification on how a properly structured ACO would implicate a law designed to address payments from a hospital to physicians. While there are scenarios under which payments might be made from hospitals to physicians, there are already protections for those arrangements when they meet the proper safeguards, and under an ACO, shared savings should be distributed only by the ACO as a whole, not by an individual hospital participating in the ACO. Simultaneously, the ACS believes that CMS and the OIG should develop safeguards to ensure that ACOs do not make payments to physicians to inappropriately limit services. We do not believe that the CMP, with or without a waiver designation, can achieve this because ACOs should be legal entities that are distinct from hospitals, and the governance structure of an ACO should by definition be different than a participating hospital's board because of the multiple stakeholders that must be represented in the ACO governance board.

MEDICARE SHARED SAVINGS PROGRAM: SOLICITATION OF PUBLIC COMMENTS ON ADDITIONAL WAIVER DESIGN CONSIDERATIONS

Arrangements related to establishing the ACO/Arrangements between or among ACO participants and/or ACO providers/suppliers related to ongoing operations of the ACO and achieving ACO goals

CMS and OIG have requested comment on whether the proposed protections should be extended to financial arrangements other than those created through the act of distributing shared savings. Because of the varied structures that are likely to be created by ACOs across the country, we understand the difficulty of creating an additional protection narrowly focused on appropriate financial arrangements. One area in which we see a need for protection, however, relates to the organizational, start-up, and training costs associated with launching an ACO. As recognized by CMS, the start-up costs of creating an ACO are not insignificant. In addition, many surgical practices, particularly small and rural practices, are already struggling to make investments in other patient care initiatives which require resources such as the Physician Quality Reporting System, the Medicare E-Prescribing Program, and the Medicare and Medicaid Electronic Health Record Incentive Programs. Given practice resource limitations, we believe it would be appropriate for CMS and the OIG to consider creating protections for ACO assistance to physician practices for start-up costs that are directly associated with ACO participation and necessary infrastructure. We believe that this would be particularly important if the current exception and safe harbor for electronic health record arrangements is not extended. While those protections might already



Administrator Berwick and Mr. Levinson

June 3, 2011

Page 4

include certain relevant arrangements and will perhaps be extended, we think it is important to create a protection that is directly related to the creation and operations of an ACO that, much like the currently proposed protections for the distribution of shared savings, would extend after the expiration of the Medicare agreement if the financial arrangement was the result of ACO activities during the duration of the agreement with CMS.

CENTER FOR MEDICARE AND MEDICAID INNOVATION: SOLICITATION OF PUBLIC COMMENTS ON WAIVER DESIGN CONSIDERATIONS

CMS requests input on how to implement waiver authority for the Center for Medicare and Medicaid Innovation (CMMI). Unfortunately, the ACS is uncomfortable providing input on the CMMI-related waiver authority at this time, especially since this input is being sought unrelated to specific CMMI demonstrations or other initiatives. We recommend that CMS consider requesting input on waivers only in relation to specific projects since we think this will be the best way to obtain meaningful information.

CONCLUSION

We appreciate the opportunity to offer these comments regarding the Medicare Shared Savings Program Waiver Designs. If you have any questions about our comments, please contact Bob Jasak in the American College of Surgeons' Division of Advocacy and Health Policy. He can be reached at bjasak@facs.org or at (202) 672-1508.

Sincerely,

A handwritten signature in black ink that reads "David B. Hoyt".

David B. Hoyt, MD, FACS
Executive Director