The Academy Advisors
515 Wythe Street
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September 27, 2010

Donald Berwick, M.D.
Administrator
Center for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20211

Dear Dr. Berwick:

We appreciate the opportunity to submit these **Suggestion s Regarding the Medicare Shared Savings Program (ACOs).** The Academy Advisors is the policy analysis affiliate of The Health Management Academy which provides educational services to many of the leading health systems in the nation. The Academy Advisors conducts policy analysis regarding issues of interest to leading health systems and provides forums for them to study and comment on important issues.

Leading health systems contributing to the development of the analysis contained in this letter include: Adventist Health System, Advocate Health Care, Aurora Health Care, Banner Health, Christiana Care Health System, Iowa Health System, New York-Presbyterian, Sharp HealthCare, Virtua Health.

Suggestions Regarding the Medicare Shared Savings Program (ACOs)

I. Eligibility as an Accountable Care Organization (ACO)

Statutory reference in section 3022:

Groups of providers of services and suppliers who have established a mechanism for shared governance and a legal structure for receiving and distributing payment may become an ACO. Entities must fit one of several practice arrangements criteria to become an ACO or be an entity designated by the Secretary.

Regulatory suggestion:

Clearly Define Eligible Entities to Serve as ACOs.

- ACOs will be most effective if they are required to have the capabilities of an integrated health system. The form of that ACO entity could be fully integrated

providers operating under a corporate parent or an entity in which hospitals, physician groups and other providers are integrated through joint venture or other legal arrangements.

- The ACO entity will be most effective if it is not be required to undergo new legal structures to operate as an ACO under the Medicare Shared Savings Program, if the current structure can:
    - Organize people and clinical systems in a patient-centric model;
    - Directly influence clinical and quality outcomes; and
    - Operate more cost efficiently than non-provider entities.
- Third party administrators, insurance companies or similar associations should not be given authority to provide the legal and governance structure to run, own or operate ACOs.

II. Requirements for Participation as an ACO in the Medicare Shared Savings Program

Statutory reference in section 3022:
I**ntegrated health systems are able to support the numerous requirements outlined for participation in the program.**

Regulatory suggestions:
Providers <u>contemplating</u> serving as ACOs need access to all Medicare claims data of prospective ACO beneficiaries, to properly assess ACO financing and staffing.

- Patient-specific and complete claims data are necessary to develop staffing models to care for the ACO beneficiary population.
- Currently, there is no mechanism available for providers to readily access these data from CMS.
- We urge the Secretary to set up a streamlined process by which an ACO qualifying entity can receive claims data (with appropriate privacy protections) regarding a potential ACO beneficiary population at a minimal cost. The ACO qualifying entity will certify, in writing, that it meets the criteria to participate in the program as defined by the law. The claims data can be directly released to the ACO qualifying entity, or to the designee of such entity used in administering the operation of the ACO, with appropriate privacy protections, on a weekly basis.

Beneficiaries should be attributed to the ACO associated with a particular primary care physician (PCP) if the beneficiary has received over 50% of their primary care services from that particular PCP or organized group of PCPs. Additionally, if a potential beneficiary does not have 50 % of his or her billable service codes with a particular PCP or organized group of PCPs, than the beneficiary should be attributed

to the ACO if 50% or greater of their combined E & M and/or preventive service codes come from a particular medical group of PCPs and/or specialists.

- However, the rules need to accommodate circumstances where ACO members cannot receive timely access to their primary care physician; have the need to go outside the ACO for emergency services; or have the need to see specialists not available in the ACO.

Providers serving as ACOs need to have access to current and complete claims data, including Part D pharmaceutical data of the patients within the ACO.

III. Quality Measures and Reporting Requirements

Statutory reference in section 3022:

Clinical processes and outcomes, patient and care giver experience and patient utilization will be among the measures used to assess the quality of care furnished by the ACO. Data on care transitions across health care settings, including hospital discharge planning and post-hospital discharge follow-up, will be measured. ACO professionals shall seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. These measures must be set forth by the Secretary in rulemaking.

Regulatory suggestion:

Accountable care quality measures should be aligned with the performance measurement initiatives set forth by CMS in the final rule on Medicare and Medicaid programs, the Electronic Health Record Incentive Program and other Value Based Purchasing Quality Measures.

Nationally recognized quality organizations such as AQF and NCQA can be helpful in developing meaningful quality data.

- The more interaction payment reforms have with each other and the more they complement each other, the more efficient it will be for healthcare providers to engage in and implement the reforms and for CMS to measure them.

IV. Payment to the ACO and Treatment of Savings

Statutory references:

PPACA authorizes several payment models for ACOs. Section 3022 authorizes the opportunity to share in demonstrated savings within a fee-for-service environment in which providers take "no risk" but can share in demonstrated savings.

Section 10307 of PPACA authorizes the Secretary to arrange for limited or substantial capitation arrangements in which payments are unrelated to the volume of services provided, to the intensity of service use, or to the frequency of face to face meetings and in which providers take on some financial risk for poor quality results or failure to control costs.

Regulatory suggestions:

Since hospitals or health systems operate under a variety of reimbursement schemes, and to encourage them to create ACO structures within the next five years, CMS should establish flexible payment arrangements.

- Hospitals or health systems need the flexibility to negotiate payment arrangements with CMS that meets both CMS goals and the goals of the health system in generating revenue to build and enhance ACO infrastructure. Differing arrangements can be authorized under the authority of Section 10307 of PPACA.

When the three years of shared savings under the Medicare Shared Savings Program ends, we urge attention be given to developing long term incentives to ensure long term viability of ACOs.

V. Participation in Multiple Shared Savings Programs

Statutory reference in section 3022:

Health care providers that participate in testing or expanding a model under section 1115A (the CMS Innovation Center) or any other program or demonstration project that involves shared savings may not participate in the Medicare Shared Savings program. Further, providers who participate in the Medicare shared savings program cannot also participate in the independence at home medical practice pilot program under section 1866E.

Regulatory suggestion:

It is advantageous to the Medicare Program for providers to participate in multiple reimbursement reforms at once.

- Coupling several payment reforms within ACOs can yield up-front funding for providers to invest in the infra-structure needed to form a sustainable ACO model for the long term.

Hospitals or health systems should be permitted to pursue demonstration or pilot programs through the Center for Medicare Innovation while also operating as an ACO under the Medicare Shared Savings Program when such models do not conflict and the Secretary finds that participation is in best interests of the Medicare beneficiaries.

- Hospitals or health systems that have affiliated regions should be able to establish multiple ACO structures which independently participate in the shared savings program.
- The same providers should be able to simultaneously participate in shared savings programs under the Medicare and Medicaid program (for example, the Medicare shared savings program and the Pediatric ACO).
- Hospitals or health systems should be allowed to participate in multiple shared savings programs under Medicare as long as the same Medicare population is not targeted
- Hospitals or health systems should be able to participate in an ACO and the Medicare Advantage (MA) program simultaneously.

VI. Beneficiary Attrition from ACOs

Statutory Provision:
The provisions of the Medicare Shared Savings Program contain no requirement that Medicare beneficiaries utilize only the healthcare professionals and providers within the ACO to which they are assigned.

Problem:
Health care providers cannot guarantee outcomes for beneficiaries if they do not provide and coordinate a substantial amount of care.
Organizations that commit to provide the total care of a defined population require the ability to monitor and have input into the health care services of the beneficiaries for which they are accountable in order to achieve quality outcomes and realize efficiencies.

Regulatory Solution:
Positive incentives for Medicare beneficiaries along with value established by ACOs can help create loyalty for the patient to seek most care within an ACO.
- The American public has accepted increased cost sharing for being treated "out of the provider network."
- If a certain ACO does not have a service needed by the beneficiary, the patient should be able to seek care outside of the ACO provider network for that service and have the benefit covered by Medicare.
- The outcomes of beneficiaries that leave the ACO provider network for a certain percentage of their care should not factor into the quality and outcome performance measurements for the ACO.
- A grievance procedure by which beneficiaries can challenge the payment or non-payment of an out of ACO provider network could be required.
- Waiving restrictions on provider telephonic and email communications with patients and giving providers the ability to waive co-payments; both contribute to a care environment desired by patients.

We appreciate the opportunity to submit these **Suggestions Regarding the Medicare Shared Savings Program** for your consideration.

Yours sincerely,

Gerald E. Bisbee, Jr., Ph.D., M.B.A.
Chairman and CEO

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Administrator
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Dear Dr. Berwick:

We appreciate the opportunity to submit these comments on **Removing Barriers to Quick and Effective Integration.** The Academy Advisors is the policy analysis affiliate of The Health Management Academy which provides educational services to many of the leading health systems in the nation. The Academy Advisors conducts policy analysis regarding issues of interest to leading health systems and provides a forum for them to study and comment on important issues.

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Removing Barriers to Quick and Effective Integration
As providers develop the organizational and legal structures required to implement ACOs, it has become clear that there are regulatory and legal barriers to operating as an ACO. Providers and government officials are addressing these barriers to integration which is appropriate and necessary for the development of ACOs by 2012 that deliver efficient and high quality care.

The ACA, section 3022(f) gives the Secretary of the Department of Health and Human Services (the Secretary) wide authority to waive the applicability of the Anti-Kickback Statute; the Civil Monetary Penalty Statue; and the Stark Law, and thus the ability to remove most of the barriers which may interfere or cause Integrated health systems to be unable to move forward with developing a successful ACO structure.

This memorandum lists specific barriers to integration below and we request that the Secretary, through rule making, will be able to exercise the full extent of her authority given by Congress to remove these barriers. Likewise, we request that the Department of Justice's Antitrust Division and the Federal Trade Commission exercise their full discretionary powers to remove the barrier of antitrust risk in the formation of federally contracted ACOs.

I. The Anti-Kickback Statute

Statutory Provision:
42 USC Section 1320a-7b(b) prohibits the knowing and willful offer, payment, or receipt of any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program.

Problem:
Multiple business arrangements, not allowed in the past, may facilitate an ACO providing patient care of high quality and low cost.

To be responsible for the health of its population, an ACO will want to encourage patients identified as part of the ACO population to receive as much care as possible within the ACO network. Coordination of care is facilitated by a patient receiving care within the network and certain fee for service practice patterns may be altered as the ACO strives to improve outcomes.

Solutions:
Integration will be facilitated if the Secretary create a broad protection for ACO providers who comply with the requirements of a federally contracted ACO.

- Such ACO providers would be permitted to:
    - Utilize cost reduction incentives (such as routine waiver of co-payments) without being subjected to prosecution under the Anti-Kickback Statute;
    - Provide incentives to enrollees to use certain efficient providers or request discounts from efficient providers in exchange for the referral of Medicare enrollees; and
    - Create gainsharing arrangements that are demonstrated to improve access, clinical quality and the efficient delivery of health care.
- Current OIG advisory opinions (i.e., OIG Advisory Opinion 8-16, October 14, 2008) that provide various safeguards from violation of the Anti-Kickback Statute are not broad enough to cover ACO arrangements or the behaviors necessitated by an ACO.
- Encourage providers to refer patients, manage patient care, and order services or supplies paid for by the governmental health care program on the basis of the patients' best health interests and not on the basis of avoiding implication of the Anti-Kickback Statute.

II. Civil Monetary Penalty (CMP) Statute

Statutory Provision:
42 USC Section 1320a-7a(b)(1). If a hospital or health system makes a payment to a physician as an inducement to reduce or limit services provided to Medicare enrollees, the hospital and physician may be subject to civil monetary penalties and exclusion from the Medicare program. In 1999, the HHS Office of the Inspector General (OIG) issued a Special Advisory Bulletin interpreting the statute to prohibit any payment that has the effect of reducing or limiting services without regard to whether they were medically necessary or appropriate. This interpretation may create a barrier to care improvement initiatives, especially the adoption of evidence based, clinical protocols.

Problem:

ACOs will seek to incent physicians to render an appropriate level of care to beneficiaries, at the appropriate time and in the appropriate care setting. The consequence may result in a lower volume of Medicare services to beneficiaries, and thus, may be construed to violate CMP laws.

The mission of an ACO is to offer more preventive services and have an overall healthier population which requires less high cost care (i.e. inpatient services). This statute makes it difficult for hospitals or health systems to incent physicians to make decisions based on medical necessity and incent physicians to lower the use of the acute (and most costly portion of the) health care system.

Solution:

Integration will be facilitated if the Secretary waive the applicability of the CMP statute to federally contracted ACOs that maintain quality and design incentive plans or clinical initiatives around reduction of costs and medical necessity decision making.

III. Antitrust Laws

Statutory Provisions:

Sherman Act, Section 1: Agreements among competitors that unreasonably restrain trade, including some exchanges of information by competitors on pricing and other types of competitively sensitive information, can be considered a violation of the Act.

Sherman Act, Section 2: If an entity achieves monopoly power by predatory or other anticompetitive acts, the conduct may violate the Act.

In 1996, the Federal Trade Commission and the United States Department of Justice issued *Statements of Antitrust Enforcement Policy in Health Care* ("*Health Care Statements*") which outline the agencies' approach to certain health care collaborations and the Agencies have also issued *Antitrust Guidelines for Collaborations among Competitors* ("*Competitor Collaboration Guidelines*"). The agencies have also issued several advisory letters interpreting the Health Care Statements which may be insufficient to give assurance to hospitals and health systems developing ACO structures that they are not violating the antitrust laws through their business relationships.

Problem: Antitrust Laws May Stand in the Way of ACO Development

Over the last ten years, several large health systems have experienced situations where they have tried to work with competitors to offer the appropriate healthcare resources to their communities by collaborating with each other on projects. For example, in several health system communities competitor hospitals sought to build a joint hospital building in the suburbs of urban areas, only to be directed by the FTC that such collaboration would result in a violation of anti-trust laws. As a consequence, many suburban settings sport multiple hospitals in circumstances where the need of the community may only support one hospital. Clearly, anti-trust laws that prohibit collaboration of healthcare providers in a manner which can meaningfully lower healthcare costs in a community need to be modified to fulfill the intent of the ACA.

A successful ACO will likely undertake process and organizational redesign that structures ACO providers to collaborate and share information with competitors to enhance coordination and preventive care, improve care transitions, and manage chronic disease. Overly restrictive interpretation of the antitrust laws might stand in the way of this transformation. While the ACOs contemplated by health care reform are organizations that are formed to cover Medicare beneficiaries, their benefits should be extended to other patient populations, including those covered by commercial insurers. The guidelines may:

- Make it difficult for providers to negotiate with health plans to be reimbursed for ACO services. Such negotiations are necessary to provide incentives for physicians to participate and to help fund the development of the program.
- Require providers to incur significant costs and time developing an ACO, rather than permitting it to begin operating with smaller initiatives and then build upon those over time.
- Limit the ability of providers in an ACO from agreeing to be loyal to that ACO.
- Interfere with the ability of the developers of an ACO to persuade providers to participate by insisting that they impose sanctions for failure to abide by the protocols of the program.
- Limit the ability of the participants in the ACO to exchange data among competing providers.

The current guidelines are difficult to draw conclusions from about what forms of integration are acceptable because the guidelines are dense and exceedingly fact specific. Seeking guidance for a particular arrangement is very expensive and time consuming. The guidelines do not address certain issues that ACO developers will face, such as coordination of care among multiple hospitals.

Solutions:

- Integration will be facilitated if the agencies do not challenge activities by providers to develop and operate ACOs that have been approved by the Secretary of Health and Human Services under the ACA unless the agencies can provide clear and convincing evidence that the ACOs have created actual anticompetitive effects with the commercial sector.
- Integration will be facilitated if the agencies provide short, plain summaries of the factors that are relevant to establishing actual anticompetitive effects, and of the guidance they have given through the advisory letters.

IV. Stark Law (and Implication of the Fraud Enforcement and Recovery Act [FERA])

Statutory Provisions:

42 U.S.C. Section 1395nn. Stark prohibits hospitals and health systems from receiving reimbursement from government health care programs arising from referrals from physicians with whom the hospitals have financial relationships (unless a Stark Law exception applies.) Generally, if the financial relationship varies with the value or volume of referrals or other business generated between the parties, the relationship is suspect under Stark. If the Stark Law is violated, the government's position is that payments for designated health services referred by the physician are to be repaid.

Enhanced Penalties for Violation in ACA: ACA Section 6402 (requiring the repayment of identified overpayments within 60 days), coupled with the Fraud Enforcement and Recovery Act (FERA) (Pub. L. No. 111-21, 123 Stat. 1617 (2009)(providing that the False Claims Act (FCA) (31 U.S.C Section 3729) is violated if obligations to the government are not repaid in a timely manner, results in a potential FCA violation for retention of overpayments for more than 60 days or periods of noncompliance with the Stark Law. Under the FCA, whistleblowers can share in any recoveries, providers can be required to pay back payments received in violation of the Stark Law and there is the potential of treble damages and criminal prosecution.

Problem:

The Stark Law may stand in the way of physician alignment which is fundamental to the development of successful ACOs

Alignment of primary care physicians with hospitals and health systems is central to the successful implementation of ACOs. Implementation requires participation of primary care physicians who agree to be held jointly accountable for improving quality and lowering spending growth for the population they serve. It is likely that additional payments to primary care physicians will be made by hospitals or health systems in exchange for physicians leading prevention, disease management and coordination of care activities that reflect best practice in primary care. The payments will not be based on hours worked or volume of patients seen.

The employment model of physicians by hospitals or health systems continues to arise as a model of choice to align incentives in a reformed delivery system. The Stark Law creates limitations on incentives and payment models within the employed physician model that may work counter to increased efficiency and quality. The Stark Law generally prohibits financial relationships between hospitals and physicians that vary by the value or volume of referrals or other business generated between the parties. This provision was designed to prevent overutilization in fee for service payment methodologies, but may be counterproductive to clinical integration and optimum referral relationships between competitors in an ACO.

Solutions:

Waive provisions of the Stark Law which are necessary to carry out the provisions of ACA. Integration will be facilitated if the Secretary:

- Deem the financial relationships, as a general rule, between physicians and hospitals or health systems exempt from the provisions of Stark, if the federally contracted ACO is in compliance with the provisions of the Medicare Shared Savings Program or the financial relationship between the hospital and the physician is consistent with ACO purpose and authority;
- Eliminate the FCA liability potential described above for ACOs which are operating in compliance with the federal statute;
- Exempt the employment of physicians by hospitals or health systems who participate as a federally contracted ACO from the provisions of the Stark Law; and
- Provide an explicit comprehensive exception under Stark that allows physicians and hospitals to coordinate the financing and use of the Electronic Medical Record

V. Health Insurance Portability and Accountability Act (HIPAA)/Health Information Technology for Economic and Clinical Health Act (HITECH)

Statutory Provisions:

42 U.S.C Section 17935(d). The HITECH Act generally prohibits covered entities or business associates from receiving remuneration, directly or indirectly, in exchange for protected health information. There are numerous exceptions to this prohibition set out in the proposed rules. The HITECH Act increased penalties for violation of HIPAA from $25,000 to $1.5 million. The Department of Health and Human Services (HHS) in the July 14, 2010 *Federal Register* proposed certain modifications to the privacy, security and enforcement requirements of HIPAA, largely to implement changes necessitated by HITECH.

Problem:

HIPAA and HITECH enhanced penalties may discourage providers from sharing health information needed to coordinate care.

The utilization of the electronic health record is an essential ingredient for the success and survival of the ACO. After ACA, numerous measuring and reporting incentives will need to be shared with providers, payers and others included within the health care delivery cycle. Sharing of patient information data in determining patient centered outcomes and measurement, evidence based medicine, evidence informed care, best practice development and implementation is all necessary. Specifically, the sharing of data to operate an ACO could be construed for financial or operational purposes as not meeting the exceptions set forth in the HITECH Act.

Solutions:

- Under the HITECH Act, the Secretary has the authority to deem the exchange of protected health information by a covered entity or business associate for remuneration appropriate and necessary. See 42 U.S.C. Section 17935(d)(2)(G).
- We recommend that the Secretary create a broad exception for the exchange of data for federally contracted ACO purposes appropriate to the operation of the ACO. Such an exception could be promulgated in the final HITECH rule set to be published in late 2010.

VI. State Statutes and Federal Pre-emption

Problem:

State laws may stand contrary to federal laws in allowing ACO development.

Certain states may have ACO-friendly statutes (states that allow the employment of physicians) while other states do not. It will facilitate wide-spread success of ACOs if all states can move uniformly to support ACO development and operation. Overcoming or changing limitations in state law that may impede ACO development could take years

Solution:

ACA 3022(f) can be utilized by the Secretary to establish, as intended by Congress, the federal presence necessary to preempt state laws that inhibit the fulfillment of the ACO provisions of ACA.

State Antitrust and Competition Statutes

Problem:

Federal authority relaxation of enforcement of antitrust guidelines may not have any effect on state enforcement efforts of similar state statutes.

Solution:

Federal pre-emption may be used to establish a federal presence and guide state antitrust statutes and enforcement.

State 'Any Willing Provider' Statutes

Problem:

Such laws may force ACO's to accept inefficient, low quality providers into the ACO provider panel.

Solution:
Clarify Congressional intent to preempt the field of ACO provider panel makeup and permit federally contracted ACO provider panels to provide services to commercially insured non-governmental health care patients.

State Insurance Laws
Problem:
Federally contracted ACOs may find that their financial operations may be contemplated and approved for government health program ACO purposes, but that various state insurance laws prohibit their operation because the operation with regard to nongovernmental patients is viewed as the business of insurance, thus subjecting the ACO to the various levels and types of health insurance regulation of the states in which the ACO provides health care.

Solution:
Integration will be facilitated if the operation of a federally contracted ACO be exempt from state insurance laws and regulation, and should be subject only to reasonable solvency standards.

State Corporate Practice of Medicine Statutes
Problem:
Such laws stand in the way of employment of physicians by large health systems and may interfere with a simple straight forward approach to alignment of physicians fundamental to ACO development.

Solution:
Clarify Congressional intent to preempt such limitations if the employer entity is federally contracted ACO.

We appreciate the opportunity to submit these comments on barriers to integration for your consideration.

Yours sincerely,

Gerald E. Bisbee, Jr., Ph.D., M.B.A.
Chairman and CEO