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ACO Legal Issues
Mail Stop C5-15-12
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir or Madam,

COMMENTS OF SUTTER HEALTH ON LEGAL ISSUES RELATED TO ACCOUNTABLE CARE ORGANIZATIONS

The following comments are submitted by Sutter Health in connection with the Federal Trade Commission ("FTC"), Department of Health and Human Services ('HHS"), Centers for Medicare and Medicaid Services ("CMS"), and Office of the Inspector General ("OIG") Workshop Regarding Accountable Care Organizations and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty Laws ("ACO Workshop").

I. Introduction

Sutter Health is an integrated health system serving patients and their families in more than 100 Northern California cities and towns. Sutter Health doctors, not-for-profit hospitals and other health care service providers share resources and expertise to advance health care quality

and access. Sutter-affiliated hospitals are regional leaders in cardiac care, women's and children's services, cancer care, orthopedics and advanced patient safety technology, and Sutter Health doctors have been recognized as among California's top performing, highest quality physicians.

Sutter Health has a long-standing commitment to investing in innovation that advances clinical integration across the care continuum. We have been recognized as among the top networks in the United States providing integrated patient care. The Sutter Medical Network, a network of nearly 5,000 physicians in Northern California, brings together physicians in Sutter medical foundations, as well as physicians in independent practice associations, who have committed to a rigorous process of working together to develop and follow clinical guidelines based on proven best medical practices, addressing nationally identified priorities for improving health care and seeking to improve affordability of health services. As a California-based health system, Sutter Health and its affiliates have substantial experience contracting with independent practice associations and operating in a capitated environment. We therefore are well-positioned to present ideas on integrated delivery systems.

Sutter Health is leading the transformation of health care to deliver high quality, affordable and efficient patient-centered care. Leadership and management from across the system is actively engaged in developing a more robust coordinated care model to ensure our organization is structured to direct a new health care system accountable for the outcomes of care and the costs associated with delivering the entire continuum of care for the patient. Sutter Health believes that it is well-positioned to serve as an Accountable Care Organization; however, regulatory relief and flexibility in designing ACOs will be critical to our, and other health systems', success.

II. Importance of Elimination of Legal Barriers to Clinical Integration

As the Federal Register notice announcing the ACO Workshop recognized, a complex set of legal requirements, including the antitrust laws, will apply to ACOs. The physician self-referral prohibitions, the anti-kickback statutes and the Civil Monetary Penalty law impose significant constraints on our ability to more efficiently and effectively integrate and coordinate the delivery of health care. Furthermore, while the antitrust laws typically would not significantly interfere with the development of programs established or approved by the Secretary of HHS to serve only Medicare beneficiaries, it is likely that the ACOs created pursuant to the Affordable Care Act will contract with private payers in addition to participating in the Medicare program. It is therefore critical that the antitrust laws be taken into account in the creation of ACOs.

The antitrust laws are implicated whenever competing health care providers collaborate to provide services to patients, especially when the collaboration involves participation in health plan networks and the negotiations with payers necessary for such participation. Given the mandated scope of ACOs under the Affordable Care Act (e.g., the requirement that they care for a minimum of 5,000 Medicare beneficiaries), it is quite likely that competing health care providers will need to join together to develop and implement ACOs to achieve the critical mass necessary to provide such broad coverage. Joint contracting with health plans will then be necessary for ACOs to be able to provide services to private pay patients.

In recent years, many health care providers such as Sutter Health have been working on programs that would clinically integrate competing health care providers to improve the quality of services provided, to contain costs, and to expand access to care. Experience has shown that the antitrust laws as interpreted by the federal antitrust agencies, as well as the prohibition on physician self-referral and the anti-kickback statutes, have created legal barriers that interfere

with the efficient development of such clinical integration programs. These comments describe those barriers and offer suggestions on how to ameliorate the problems.

III. ANTITRUST: Current State of the Law and Antitrust Agency Guidelines

As has been repeatedly recognized by the federal antitrust enforcement agencies, the antitrust laws do not prohibit legitimate competitor collaborations. Indeed, the agencies recognize that such collaborations are often not only permissible but procompetitive.[1] Unfortunately, guidance issued by the federal antitrust agencies to health care providers over the years has been unduly restrictive, and has inhibited the development of efficient, clinically-integrated organizations.[2]

The current guidelines, as interpreted by FTC Advisory Opinions, establish a rigorous set of requirements for the creation of clinically-integrated provider networks. Networks that meet these requirements may engage in collective negotiations with health plans without engaging in *per se* illegal conduct. If they do not satisfy these requirements, however, networks risk being accused of price fixing.

As detailed in the next section, these guidelines are unduly restrictive and create limitations on the ability of health care providers to create effective clinical integration programs for commercially insured patients. These limitations will significantly hinder the development of effective ACOs if they are allowed to remain in place.

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[1] Antitrust Guidelines for Collaborations Among Competitors, Issued by the Federal Trade Commission and the U.S. Department of Justice (April 2000).

[2] *See, e.g.*, Statements of Antitrust Enforcement Policy in Health Care, issued by the FTC and the Department of Justice Antitrust Division in 1993, and most recently updated in 1996; Tri-State Health Partners, Inc. Advisory Opinion (April 13, 2009); Greater Rochester Independent Practice Association, Inc. Advisory Opinion (September 17, 2007); Suburban Health Organization, Inc. Advisory Opinion (March 28, 2006).

IV. Barriers to Clinical Integration Created By the Antitrust Guidelines and Recommendations for Change

It is critical to eliminate the key barriers to the formation of clinically-integrated networks. The risks of violating the antitrust laws have a chilling effect on the creation of procompetitive networks composed of competing health care providers. Providers who guess wrong about what is permissible face the prospect of federal government investigations and the potential for private antitrust litigation. And seeking guidance from the government is not an option. The advisory opinion process is costly and lengthy, and certainly could not be completed in a reasonable time frame consistent with the need for prompt development of an ACO.

Taken as a whole, the guidelines create a number of significant barriers to the creation of the type of clinically-integrated organization that is contemplated by the Affordable Care Act. The clearest and best way to remove those barriers is for the antitrust enforcement agencies to issue an enforcement policy that declares that all ACOs that are approved by the Secretary of HHS will be analyzed under the rule of reason, even in the commercial sector. This would most directly support the policies of the Affordable Care Act and lead to the most effective development of ACOs. By definition, ACOs are the type of efficiency-enhancing organizations that should qualify as clinically-integrated networks. An ACO is an "organization of health care providers that agree to be accountable for the quality, cost, and overall care" of a patient population (i.e., Medicare beneficiaries); this matches the definition of clinical integration (a program that "create(s) a high degree of interdependence and cooperation among the physicians to control costs and ensure quality"). Accordingly, if an ACO contracts with private payers, it should be entitled to rule-of-reason treatment. To the extent that market power issues are of concern, these can be taken into account in the rule-of-reason analysis.

If this simple and straightforward approach is not taken, the antitrust enforcement agencies should at the very least amend the guidelines to smooth the path toward implementation of clinically-integrated networks. It would be best for these amendments to apply to all clinical integration efforts, regardless of whether they are initially undertaken in the context of developing an ACO, because all clinically-integrated networks have the potential to create efficient organizations for the delivery of health care. At a minimum, however, these amendments should apply to ACOs approved by the Secretary.

A. Cost and Time to Develop Networks

The current guidelines require providers to incur significant costs ("the significant investment of capital, both monetary and human") and undertake activities that require a substantial time commitment before even beginning to negotiate with payers. Examples given in the guidelines make clear that a program must be completely developed before negotiations begin and that it be comprehensive – the providers may not start with a few smaller initiatives (such as disease management for specific diagnoses) and then graduate to a more comprehensive program.[3]

The guidelines should be amended to permit a network to engage in discussions with payers – including price negotiations – at the outset of the development of a clinical integration program. This would immediately lower the costs of developing the program at the front end, and encourage providers and payers to work together to create incentives for provider participation in efforts to improve quality and manage the costs of care.

[3] See Statement 8 of the guidelines at 73, 86; Statement 9 of the guidelines at 131.

B. Sanctions for Failure to Follow the Standards and Protocols of the Network

The guidelines currently require that serious sanctions must be part of the process of managing the care provided by physicians. The guidelines state that these sanctions should include the threat of expulsion from the network: "Network participants who fail to adhere to the network's standards and protocols will be subject to remedial action, including the possibility of expulsion from the network." But this requirement interferes with a network's ability to persuade physicians to participate, and does not permit any flexibility in deciding how best to ensure adherence to the standards and protocols that have been developed. Sutter Health's experience has shown that education and data analysis are often sufficient to persuade physicians to adhere to these protocols.

C. Exchange of Information

To establish a robust clinical integration program it is essential for the providers forming the network to have access to data about practice patterns, referral trends and the patient populations cared for by the physicians in the network. But information exchange guidelines unduly restrict the types of data that can be exchanged among providers, approving only those exchanges facilitated by a third party.[4] For example, claims data is probably the most useful source of this information, but because it contains some rate information the guidelines limit the ability of providers to have access to each other's data.

The guidelines should be amended to eliminate restrictions on sharing claims data in the context of developing a clinical integration program. The data is rarely kept in a format that would lend itself to collusion among competing providers, and it can be used by data analysts to

[4] See Statement 6 of the guidelines (Exchanges of Price and Cost Information) and Statement 8 at 79.

provide the information needed to develop practice protocols without giving the providers an undue amount of insight into pricing.

D. Exclusivity

The guidelines frown upon exclusive networks, and make the formation of an exclusive network with more than a 20% market share unduly risky.[5] But there are numerous benefits to having an exclusive network, some of which are listed below:

1. A robust electronic health records system (EHR) is critical for the development of an ACO and other forms of clinical integration. But if providers are not exclusively connected to one network, they will not be able to share a single EHR platform. There is insufficient interoperability among different EHR systems to permit easy participation in more than one network.

2. If providers are not exclusive to a single clinically-integrated network, it will be far more difficult for them to adhere to the practice protocols and standards of the networks in which they participate. If they are forced to follow differing and potentially inconsistent sets of protocols, the benefits of standardization of care will be lost.

3. One of the benefits of clinical integration is that providers can manage the care of their patients in a consistent fashion. In an exclusive network, primary care physicians will be able to refer their patients to a set group of specialists, and will be able to work with those specialists for all of their patients. If a network is not exclusive, the primary care physicians will not have one established group of specialists to whom they can refer, and will therefore not be sure that patient care will be consistent.

The federal enforcement agencies should amend the guidelines to be more flexible on exclusivity. At a minimum, the market share threshold for a safety zone should be increased – in

[5] See Statement 8 at 64-67; see also Suburban Health Organization, Inc. Advisory Opinion.

many communities there will be too few providers to stick with a 20% limitation. (It is unlikely that most communities will be able to support – or will even need – five ACOs, which is what the 20% share implies.) If the threshold is raised to 35%, that still would mean that nearly two-thirds of the providers in a community would be able to form another ACO or remain independent. The agencies should also make clear that exclusivity for an ACO with an even higher market share is not necessarily unlawful if that exclusivity is necessary to achieve the efficiency-enhancing objectives of the ACO.

In sum, a clear rule that HHS-approved ACOs will be reviewed under the rule of reason is the best way to promote the development of high quality, cost-effective networks. Absent such a rule, the antitrust enforcement agencies should implement the amendments to the guidelines described above.

V. Prohibition On Physician Self-Referral:

The Stark law prohibits a physician from referring a patient to an entity for certain "designated health services" payable by Medicare if the physician or his/her immediate family member has a financial relationship with the entity – unless an exception applies. There are a few Stark law "exceptions" that apply to service arrangements between hospitals or other entities and physicians. However most of those exceptions prohibit compensation arrangements that take into account "the volume or value of referrals or other business generated" by the referring physician or between the parties. This safeguard is clearly intended to limit the ability to link economic incentives to referrals for unnecessary services, particularly where no service is needed or a less expensive service could be as appropriate. But because the term "referral" is defined so broadly in the Stark law, this restriction could be read to apply even to situations in which a physician orders a good or service for a hospitalized patient where the hospital does not stand to

gain any additional reimbursement under the inpatient prospective payment system. Or the limitation could be read as prohibiting a hospital from including, in a physician services arrangement, an incentive for avoiding unnecessary readmissions, even if the readmission rate target is based on standards recognized by CMS. The Stark prohibition could even be read to preclude paying incentive compensation to a physician who helps a hospital achieve top rankings on CMS's own National Hospital Quality Standards, for example, if requesting an aspirin for an AMI patient at a hospital is deemed to be a "referral" of a hospital service. This is a reading of the Stark Law that CMS surely did not intend.

The Stark regulations have never effectively addressed evolving patient quality standards, and the incentive compensation that could be tied to objective patient centered quality and efficiency measures. Increasingly, objective and measurable care pathways and processes have been established by national and state standards setting organizations to promote and ensure high quality care in both the hospital and ambulatory care setting. Some of these quality benchmarks are recognized by CMS itself and some have been incorporated into CMS's own quality reporting rules and systems. And yet the Stark regulations have not kept pace with these patient-centered trends.

In states like California, which continues to have a prohibition on the corporate practice of medicine, the available Stark exceptions are even more limited, because in most cases a hospital or other health facility cannot directly employ a physician to provide professional medical care. Thus the Stark "bona fide employment relationships" exception is applicable only in limited circumstances.

As the rules for accountable care organizations (ACOs) are developed, we urge CMS to create a pragmatic Stark exception for compensation arrangements between or among

participants in an ACO that will allow ACOs to implement the cost-savings and quality goals that are necessary to make ACOs a success. Specifically, we would encourage CMS to adopt an exception that would require the ACO's compensation arrangements to be for identifiable services, in writing, signed by the parties, commercially reasonable in the absence of referrals, and not violate the anti-kickback statute, or other federal or state laws. The exception should not have a fair market value requirement, because an organization that is focused on saving costs will have a built in incentive to limit payments for services. A commercial reasonableness requirement would mitigate any possible concerns about whether there is a legitimate need for services provided under such an arrangement. The exception should not have a "set in advance" or 12 month requirement, because the ACO's arrangements need to be flexible enough to change, when necessary, to incorporate updated quality goals established by applicable standards setting bodies. As quality standards evolve and are augmented over the coming months and years, a "set in advance" or 12 month rule could present an insurmountable challenge to the ACO, because it will need to properly document and obtain internal governance approvals, and draft and execute new agreements or amendments with updated standards. If this process is carried out responsibly by an ACO, it will necessarily take some time. However, the updated standards should become effective at the time they are implemented by the third party standards setting organization. Therefore, the ACO must have the ability to implement new standards immediately, and the necessary amendments to agreements can be put in place as soon as practicable, but not necessarily "in advance" and not necessarily for a 12 month term.

This exception should encompass both direct and indirect compensation arrangements between participants in an ACO. It should permit the parties flexibility in designing quality and efficiency goals that are best suited to the patient population the ACO serves and that are best

designed to achieve savings. We believe a one-size-fits-all approach to quality incentive goals is not feasible, or in the best interest of patients, because the ACO must have the ability to meet the needs of its patient population, with, for example, innovative disease management programs for chronic conditions that are prevalent in the community. In addition, the ACO should be able to incorporate state clinical quality measures such as California's Integrated Healthcare Association's pay-for-performance goals, which many California organizations have already implemented for commercial HMO plan members.

The Stark law exception should also afford the opportunity to provide training and education to participants in the ACO that relates to the care of the patients served. In other words, the value of such training and education should not have to count toward the limit on "nonmonetary compensation" under 42 CFR 411.357(k). This exception should also extend to any electronic health record items and services that a participant may wish to provide to other participants in the ACO or, at a minimum, the existing exception in 42 CFR 411.357(w) should be extended beyond December 31, 2013.

We believe a Stark law direct and indirect compensation exception must exist independent of any exception that is developed for employment arrangements and any exception that CMS develops for direct and indirect ownership interests in ACOs, because in some states and in some systems (such as tax-exempt health systems) ACOs will need to be structured as contractual arrangements that do not involve employment or ownership in a joint venture entity.

VI. Civil Monetary Penalty Law:

The Civil Money Penalties law prohibits hospitals from offering inducements to physicians that might reduce or limit services to Medicare beneficiaries. Consequently, the

threat of CMPs reinforces the misaligned or conflicting financial incentives between physicians and hospitals that hinder efficiency and effectiveness in the Medicare program today and, further, creates an obstacle to the better-coordinated care and cost savings sought by the ACO concept. In many respects, the CMP law is the obverse of the Stark law in that it was designed to safeguard against economic incentives designed to compensate a provider for not providing needed care, rather than incentives that encourage referrals for unnecessary services. Unlike the Stark law, the CMP law does not have exceptions that define acceptable business arrangements between hospitals and physicians.

The CMP law is rooted in public and Congressional concern that managed care plans and prospectively paid hospitals would limit access to care in pursuit of profits. Congress later amended the law to permit Medicare managed care plans to reward physicians based on a combination of high quality and efficient utilization of care, but did not extend that opportunity in the fee for service arena. In the years since, CMS and the healthcare industry have developed quality standards and quality-based payment models for fee-for-service providers, concepts that simply did not exist when the CMPs originated, but the ban on giving physicians incentives to work with hospitals on improving efficiency remains.

The OIG has made it clear that they believe any hospital programs to manage utilization through physician incentive plans could be suspect. The enforcement agency has stated that any efforts to reduce services, including those that cannot be tied to a specific patient or that seek to reduce medically unnecessary services, could subject a hospital to CMPs. Although unnecessary tests and treatments carry their own risk of harm to patients, under the current CMP rules, hospitals and physicians are not permitted to collaborate on programs that would improve quality of care and reduce costs by avoiding them.

The narrow exceptions that the OIG has permitted in its advisory opinions on gainsharing, such as programs aimed at savings through standardization of surgical supplies, are laudable but insufficient to achieve the goals of the ACO model. In order to reduce the costs of care while improving quality, ACOs will have to use a variety of strategies aimed at shifting care away from the inpatient hospital setting, where the bulk of Medicare spending takes place, minimizing the use of items and services that are of doubtful benefit to the patient, and improving efficiency in all settings, from the primary care physician's office to the hospital to post-acute care. Any of these activities include the possibility that services to Medicare beneficiaries might be reduced or limited.

We urge CMS to give ACOs of all types flexibility in designing programs that realign physician and hospital incentives for providing more effective care at lower costs by issuing guidance on how ACOs can create appropriate physician incentive plans that would not trigger the CMP law.

VII. Anti-Kickback Statue:

The anti-kickback statute also prohibits payments to induce patient referrals or over-and-under-utilizing services to Medicare and Medicaid patients. As interpreted by the OIG, any incentive that may result in a reduction in care, and conceivably includes shared savings with physicians, implicates this law.

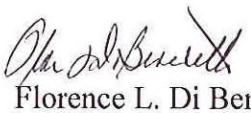
The anti-kickback statute has a safe harbor for employment of physicians; however California has a ban on the corporate practice of medicine which prohibits our system from taking advantage of this safe harbor. For an ACO to be successful, hospitals and physicians must be clinically integrated and their incentives must be aligned. We urge CMS to develop an "ACO safe harbor" that is identical to the Stark Law exception and, that would allow California

integrated delivery systems to develop clinical integration and shared savings under the ACO delivery model notwithstanding the corporate practice prohibition.

VIII. Conclusion

Thank you for considering these comments. Sutter Health would be happy to discuss these further after the ACO Workshop if the FTC is interested in additional detail. If you have questions about these comments or would like to engage in additional discussions, please do not hesitate to contact me.

Sincerely,



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