Sutter Health
*With You. For Life.*

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May 26, 2011

The Honorable Christine Varney
Assistant Attorney General
Antitrust Division
United States Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, DC 20530

The Honorable Jon Leibowitz
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

*Filed Electronically*

**SUBJECT: SUTTER HEALTH COMMENTS ON THE PROPOSED STATEMENT OF ANTITRUST ENFORCEMENT POLICY REGARDING ACCOUNTABLE CARE ORGANIZATIONS PARTICIPATING IN THE MEDICARE SHARED SAVINGS PROGRAM, MATTER V100017**

Dear Assistant Attorney General Varney and Chairman Leibowitz:

Thank you for the opportunity to provide comments on the proposed statement of antitrust enforcement policy regarding accountable care organizations participating in the Medicare Shared Savings program.

Sutter Health ("Sutter") is an integrated health system serving patients and their families in more than 100 cities and towns throughout Northern California—one of the nation's most diverse regions. Sutter is focused on achieving its vision to lead the transformation of health care to deliver high quality, accessible, affordable and efficient patient-centered care and has embraced the concept of accountable care as a critical component

of our transformation effort. Leadership and management from across the system are actively engaged in developing a more robust integrated care model to ensure our organization is structured to become a health care system for the future that is accountable for the outcomes, experience, and the associated costs throughout the entire continuum of care.

Sutter has a long-standing commitment to invest in innovation that advances clinical integration across the care continuum. We have been recognized as among the top networks in the United Sates providing integrated patient care. The Sutter Medical Network, which includes over 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 performance standards based on proven best practices, addressing nationally identified priorities for improving health care and the affordability of health services.

Based upon our experience in developing models of coordinated care, we are pleased to present these comments in response to the Federal Trade Commission and Department of Justice ("the Agencies") Notice with comment period for the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations ("Proposed Statement").[1]

## I. Introduction

There are a number of useful concepts in the Proposed Statement that will promote the development of Accountable Care Organizations ("ACOs"). Nevertheless, certain aspects of the Proposed Statement remain problematic.

The Proposed Statement makes clear that any ACO that has met the rigorous CMS eligibility criteria enunciated in the CMS Medicare Shared Savings Program: Accountable

[1] 76 Fed. Reg. 21894.

Care Organizations Proposed Rule ("CMS Proposed Rule") will be entitled to Rule of Reason scrutiny of its conduct under the antitrust laws. Under the proposal, ACOs will be secure in their knowledge that if they devote time and expense to developing an ACO plan, the Agencies will not summarily conclude that their structure is *per se* unlawful. This will encourage the formation and ultimate success of ACOs.

Another useful provision is the Antitrust Safety Zone for ACOs with a primary service area ("PSA") share of below 30%. Maintaining the Safety Zone concept, which was present in Statement 8 of the 1996 Statements of Antitrust Enforcement Policy in Health Care ("1996 Health Care Statements"), provides continuity with the non-Medicare Shared Savings regime and comfort for those ACOs least likely to raise antitrust concerns.

A third positive aspect of the Proposed Statement is the recognition on the part of the Agencies that exclusivity does not always indicate anticompetitive behavior and, in fact, can be beneficial in certain cases, such as with primary care physicians. Sutter applauds the Agencies for their recognition that exclusive arrangements may actually promote competition under certain conditions. We urge the Agencies, however, to eliminate the prohibition in the Safety Zone on exclusivity for hospitals with PSA shares below 30%. As discussed below, exclusive arrangements with hospitals can have procompetitive benefits similar to those for physicians, and do not have an unnecessarily negative impact on competition where there are other hospitals available to contract with payers or participate in other ACOs.

Despite the beneficial aspects of the Proposed Statement, Sutter remains concerned about the process and requirements it creates. We address two key issues: how the proposal converts traditional antitrust enforcement into a regulatory process and how the Proposed

Statement may operate to undermine many of its stated goals. We also include recommendations for improvements to the Proposed Statement.

To summarize, we recommend the following changes to the Proposed Statement, and we address each of these in detail below:

- First and foremost, we recommend that the mandatory antitrust review for certain ACOs be transformed into a voluntary program, so that potential ACOs that wish more guidance can obtain it. We also recommend that the voluntary review be implemented in a far less burdensome manner, by requiring ACO applicants to submit a less detailed and burdensome set of information, described below, that the Agencies could review to identify potentially problematic ACOs.

- If the current structure is maintained, it should be reframed to make it more likely to achieve the goals of the program. The 50% threshold for mandatory review is overbroad and should be modified. The Rural Exception is too narrow and should be expanded to permit single physician groups (rather than just single physicians) to be added to an ACO.

- Using Medicare fee-for-service payment data as the basis for calculating PSA shares may overstate or understate shares of commercial patients and/or overall shares, given that numerous providers will not be included in the data. Accordingly, the Agencies should reconsider the use of Medicare fee-for-service data for this purpose.

- The concept of exclusive contracting is more complicated than the Proposed Statement suggests. As long as providers are available to contract directly with health plans, an agreement to contract with only one ACO should not be troublesome, absent an unduly large market share. We recommend that the Agencies reconsider the prohibition on exclusivity for hospitals in the Safety Zone.

- The Proposed Statement does not explain what the Agencies will do to evaluate an ACO once it begins the mandatory review process, and what an ACO with over a 50% PSA share can show to demonstrate it is not anticompetitive. We recommend that the Agencies provide guidance on how they will conduct the mandatory review.

- The concept of re-review also lacks clarity. We recommend that the Agencies explain the process for re-review and clarify the circumstances under which re-review will be required.

## II. The Proposed Statement, as Incorporated Into the CMS Regulations, Transforms Antitrust Enforcement Into a Regulatory Scheme

While the increased coordination between CMS and the Agencies is a positive development, CMS's decision to make its approval of a proposed ACO contingent on that ACO obtaining antitrust clearance transforms an antitrust enforcement process into regulation. Enforcement has long been distinct from regulation, particularly with regard to antitrust. Antitrust enforcers have always operated through enforcement, taking a market as it is and monitoring whether certain actors are engaging in wrongdoing. If the government uncovers a violation, it will bring an enforcement action to stop the illegal conduct. By contrast, regulation involves creating rules that apply to all actors and that are meant to discourage or stop wrongdoing before it occurs.

In practice, whether dealing with relatively borderline anticompetitive behavior or the most egregious *per* se illegal conduct, the Agencies generally do not proscribe specific types of collaborations up front; rather, they evaluate conduct in the marketplace and then bring a case to challenge conduct that they believe is anticompetitive. Even in instances where antitrust enforcement may appear to be more regulatory in nature, such as Hart-Scott-Rodino review in the merger context, the Agencies must still go to court to stop a merger – it is not a decision that can be made by the Agencies (or agency staff) alone. Even the Agencies' advisory opinions and business review letters do not prohibit conduct; they simply state the relevant agency's enforcement intentions.

By incorporating the Proposed Statement into the proposed CMS regulations, CMS and the Agencies have transformed antitrust enforcement of ACOs into a regulatory approval process. This effectively shifts the burden of antitrust review from the government to ACO participants. And ACO participants bear a greater burden than in a typical antitrust

investigation, because the Proposed Statement does not appear to contemplate submission of information by third parties.

We suggest that this approach is unnecessary. The Agencies have sufficient experience investigating and bringing cases in the health care context to be able to identify potential violations of the antitrust laws by ACOs.[2]

Accordingly, we recommend that the Agencies transform the antitrust review into a voluntary program, so that potential ACOs that wish more guidance can obtain it. We also recommend that the voluntary review be accomplished in a manner that is far less burdensome than the approach adopted in the Proposed Statement. ACO applicants seeking a review could be required to submit a much less detailed and burdensome set of information that the Agencies could evaluate to identify potentially problematic ACOs. For example, submission by an ACO applicant of a list of participating providers, the services they provide, and where they operate, and a list of payers with which they contract should provide sufficient information for the agencies to investigate the potential competitive implications of a proposed ACO. This would also make it much easier for the Agencies to stick to their commitment to conclude the review in 90 days.

[2] CMS has stated that this regulatory approach is important because it avoids disrupting the Shared Savings Program by immunizing all approved ACOs from antitrust challenge during the three-year approval period. *See* CMS Proposed Rule, 76 Fed. Reg. 19630. Of course, that assumes that a large enough number of ACOs will be found to be anticompetitive to actually disrupt the program. Moreover, the rule already contemplates that an ACO could be removed from the program for a number of reasons, including mandatory antitrust re-review in the event of a "significant" change in ACO composition. 76 Fed. Reg. 19626. Indeed, the Patient Protection and Affordable Care Act of 2010 itself recognizes that an agreement can be terminated before the end of the three-year period. ACA § 1899(d)(4).

## III. The Proposed Statement Falls Short of Its Own Stated Goals

The Proposed Statement sets forth a number of important goals, including providing a "streamlined analysis"; a desire to "achieve for many consumers the benefits Congress intended"; and an intent to "clarify the antitrust analysis" of ACOs. Sutter supports each of these goals; unfortunately, the Proposed Statement may operate to undermine them.

### A. While the Proposed Statement attempts to create a streamlined analysis, the process as designed will in fact be extremely burdensome and costly for ACO applicants

As an initial matter, the three-step process for calculating PSA shares of an ACO's common services[3] will require a tremendous amount of work simply to ascertain whether or not an ACO is subject to mandatory review. Even though the Proposed Statement contemplates that CMS will publish data for some of the required calculations, sorting through all the data to determine the ACO's share of each common service will be extremely time-consuming and expensive, even assuming the data from CMS are clean and accurate. We note that the example of a PSA calculation in the Proposed Statement's Appendix oversimplifies to the point of being unrealistic; it is not likely that the only members of an ACO will be two hospitals, and that these hospitals will offer only 10 services each with only two in common. In reality, an ACO could include not only multiple hospitals, but also a number of outpatient facilities and several independent physician groups, which collectively could offer far more than 10 services. Indeed, there are 25 MDCs, 55 MSCs and 31 outpatient treatment categories, each of which could be a potential common service for an ACO. Thus, these threshold calculations will impose a far greater burden than the Proposed Statement envisions.

[3] 1. Identify each service provided by at least two independent ACO participants; 2. Identify the PSA for each common service for each participant; and 3. Calculate the ACO's PSA share for each common service in each PSA from which at least two ACO participants serve patients for those services.

Further, the CMS data will not take into account specialties, like obstetrics and pediatrics, which are infrequently used by Medicare beneficiaries and thus would not be kept in any sort of centralized manner. Thus, to even identify all the physicians in a PSA offering such services, let alone to calculate a given ACO's PSA share, would be extremely burdensome, if not impossible.

Moreover, for all but the largest and most sophisticated physicians' offices, merely determining the physicians' PSAs from patient zip codes and then matching that to billing codes will prove a virtually insurmountable task. Many small offices have no electronic records and would have to pay a consultant (or their billing service) to compile the information or do it manually themselves.[4]

Not only is this approach unnecessarily complicated, it also is inconsistent with existing case law. While the Proposed Statement does not purport to define relevant markets, it nonetheless uses PSAs as proxies for markets. But antitrust case law defines markets based on where consumers can turn for services offered, not simply on where providers get their patients.[5] Moreover, in a number of hospital merger cases, the courts considered 90% service areas as one starting point for geographic market definition.[6] Similarly, on the product market side, the Proposed Statement seems to reject the cluster market approach the government has

[4] Other regulatory prohibitions, such as the anti-kickback and Stark laws, would very likely prevent a hospital from funding this analysis undertaken for physicians with whom the hospitals have a financial relationship.

[5] *See Bathke v. Casey's General Stores, Inc.*, 64 F.3d 340, 346 (8th Cir. 1995).

[6] *See California v. Sutter Health*, 84 F. Supp. 2d 1057, 1069 (N.D. Cal.) *aff'd* 217 F.3d 846 (9th Cir. 2000); *FTC v. Freeman Hosp.*, 911 F. Supp. 1213, 1218 (W.D. Mo.) *aff'd* 69 F.3d 708 (8th Cir. 1995); *United States v. Mercy Health Servs.*, 902 F. Supp. 968, 977 (N.D. Iowa 1995) *vacated as moot* 107 F.3d 632 (8th Cir. 1997).

embraced in the hospital merger context[7] in favor of a far more granular product market focused on specific service lines.

Compounding the burdensome calculation exercises, the Proposed Statement frontloads the review process to an unnecessary degree. From purely a cost perspective, ACO participants will be required to spend significant money and resources up front with no certainty that the undertaking will better their chances of becoming an ACO and for reasons wholly unrelated to whether or not they will be able to achieve benefits for Medicare beneficiaries. Indeed, the up-front burden is imposed on all ACO applicants, even those that ultimately clear the PSA screens, because there is no way to know in advance whether a particular ACO might trigger mandatory review in one or more service lines.

In addition, if an ACO is required to undergo the mandatory review, the Proposed Statement requests a multitude of documents and data, with virtually no crossover with the sizeable amount of information already required to be submitted to CMS as part of the ACO application – and does not include the expenditure of resources required to respond to requests for additional information and engaging with the Agencies.[8] Then, the Proposed Statement requires a full-blown antitrust analysis by those ACOs that cross the mandatory review threshold in order to be prepared to explain to the Agencies why the 50 % trigger does not mean that an ACO is anticompetitive, even though at this point in the review there will still not have been any allegation of wrongdoing.

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[7] *See Sutter Health*, 84 F. Supp. 2d. at 1067; *Freeman Hospital*, 911 F. Supp. at 1226-27; *Mercy Health*, 902 F. Supp. at 976.

[8] For example, Item 4 in the list of documents to be provided requires the submission of "documents showing the formation of any ACO or ACO participant that was formed in whole or in part, or otherwise affiliated with the ACO, after March 23, 2010." Read in conjunction with the requirement that the ACO "represent in writing that it has. . . provided all responsive material" (Proposed Statement footnote 34), the quantity of documents required to be produced can be quite large.

Another area that creates unnecessary problems for ACOs is the requirement that an ACO applicant submit its entire application to the Agencies 90 days before it submits its CMS application: according to this rule, if an ACO has assembled its submissions for both antitrust and CMS review at the same time – a perfectly reasonable course of action – it nonetheless must hold back its CMS application for 90 days after submitting its antitrust review materials. Thus, the antitrust review has the potential to slow down the CMS review process by three months. We request that the Agencies' consider whether their review can be conducted during the time that CMS is also reviewing the application.

Again, these problems could be solved with the simpler, more streamlined approach suggested above.

### B. The Proposed Statement does not achieve the benefits Congress intended

Congress created the Medicare Shared Savings Program to incentivize providers to create ACOs that lower cost and improve treatment, but the Proposed Statement throws up numerous roadblocks that may chill the formation of ACOs. There are a number of filters in the Proposed Statement that are not narrowly tailored enough to achieve their intended purpose; while they are designed to function as screens to weed *out* ACOs that pose no threat, they will actually end up sweeping *in* large numbers of ACO applicants, many of which likely present no competitive concerns. As a result, they will discourage many ACOs from even applying to the Shared Savings Program.

For example, the Mandatory Review threshold of 50% is too low -- it is likely that there are few places outside major metropolitan areas in which the combined PSA share of an ACO would not exceed 50% in at least one specialty. And this low threshold, coupled with the strict

rule that a PSA share in excess of 50% in even a single common service requires mandatory antitrust review, could create many unintended consequences. For example, an ACO could have a combined PSA share of greater than 50% in only non-Medicare services; thus, an ACO could end up getting disqualified from the Medicare program based on a high share in pediatric services. Similarly, the decision to make MDCs synonymous with services fails to recognize that some MDCs are made up of as many as 80 DRGs, meaning that an ACO could appear to have a high common share in a particular MDC even though the shares in any given DRG do not cross the threshold.[9]

Using Medicare fee-for-service payment data as the basis for calculating PSA shares also presents problems, as it may overstate or understate shares of commercial patients and/or overall shares, resulting in procompetitive ACOs getting disqualified based on incorrect data (or, for that matter, anticompetitive ACOs being overlooked). For example, physicians who choose not to see Medicare patients, or who see few Medicare patients, are not in the CMS data the Agencies propose that ACOs use for calculating PSA shares, so the shares of those physicians will be understated. In addition, services provided to Medicare patients on other than a fee-for-service basis are not in the CMS data. In many areas of the country, Medicare Advantage plans are significant; physicians who provide services to Medicare Advantage patients will also be undercounted. This problem will be particularly apparent in California, where Sutter operates, due to the presence of the Kaiser system. Kaiser Permanente, one of the biggest health care systems in California, does not provide services to Medicare beneficiaries on a fee-for-service basis, so Kaiser providers will be left out of any calculation based on Medicare fee-for-service data. The Agencies should reconsider the use of this methodology.

[9] For example, cardiac surgery is in the same MDC as lower level cardiology services. This could cause a two-hospital ACO to cross the 50% threshold simply because one hospital receives significant revenues from its cardiac surgery program, even though the second hospital does not offer cardiac surgery.

The Rural Exception too, appears unnecessarily narrow. From the wording, the exception applies only to a single physician per specialty per county, not a single physician group. Presumably, the Agencies did not intend to require a three-person physician group in a rural country to be ineligible for the Rural Exception. The Proposed Statement should be corrected to allow the exception to apply to single physician *groups* per specialty per county. The Agencies should not be concerned that expanding the Rural Exception to include physician groups will provide a greater opportunity for anticompetitive behavior as long as the physician groups, like the individual physicians and hospitals looking to make use of the Rural Exception, will have to contract with payers on a non-exclusive basis.

In addition, the review process as articulated applies regardless of the type of payment negotiated with payers (e.g., fee-for-service, capitated) and regardless of whether there are joint fee negotiations (e.g., an ACO with a few independent specialists that would use a messenger model for those physicians or where those specialists have their own contracts). This stands in contrast to the 1996 Health Care Statements in which the type of payment affects the treatment physician networks receive from the Agencies. Thus, while ACOs were created to foster clinical integration, the standards developed in the Proposed Statement are, in some ways, less forgiving than the standards of the 1996 Health Care Statements.

Finally, the concept of exclusive contracting is more complicated than the Proposed Statement suggests: while exclusivity in the sense of a payer not being allowed to contract with a provider other than through an ACO certainly may pose potential competitive problems, the notion of a provider agreeing to contract with only one ACO while still remaining free to contract directly with health plans does not immediately appear problematic and could even promote some of the goals of ACOs with respect to coordination of care. Absent a large

market share, this type of exclusivity can be procompetitive. We therefore recommend that the Agencies reconsider the prohibition on exclusivity for hospitals in the Safety Zone.

### C. Rather than clarifying the analysis, the Proposed Statement is silent on how certain ACOs will be analyzed

The Proposed Statement does not explain what the Agencies will do to evaluate an ACO once it begins the mandatory review process, and what an ACO with over a 50% PSA share of common services can show to demonstrate it is not anticompetitive. The Proposed Statement does state that ACOs subject to mandatory review can reduce the likelihood of antitrust concern by avoiding five types of conduct, but there is no further guidance about how to distinguish among ACOs with high PSA shares to determine which may be anticompetitive and which may be competitively benign.

Another area lacking in clarity is that of re-review. While the Proposed Statement does not mention the process for re-review, the CMS Proposed Rule states that if at any time during the three year agreement period, there occurs a "material" change in the participant and/or provider/supplier composition, the ACO must notify CMS within 30 days and recalculate its PSA shares for common services; if any PSA share is greater than 50%, there will be mandatory antitrust re-review of the ACO.[10] An ACO participant that is, for example, considering adding a new specialty, will need to know under what circumstances such an alteration might trigger re-review, and no guidance is given in either the CMS Proposed Rule

[10] The precise circumstances requiring re-review are difficult to discern. For example, Section 425.21(a)(1) of the CMS Proposed Rule states that "During the 3-year agreement, an ACO may remove, but not add, ACO participants . . . and it may remove or add ACO providers/suppliers." Section 425.4 defines a participant as a provider or a supplier, indicating that an ACO both can and cannot add providers and suppliers during the 3-year period. Similarly, also in section 425.21, this time in subsection (a)(2), the Rule requires that an ACO notify CMS within 30 days of any "significant change, as defined in paragraph (b) of that section. Paragraph (b) defines a significant change to mean, among other things, "a material change as defined in §425.14" of the Rule. Upon examining section 425.14, one finds that, in subsection (a)(4), a "material change" is defined as a "significant change (as defined in § 425.21(b))."

or the Proposed Statement. Moreover, the timing of re-review after a significant change is unclear; while CMS requires notice within 30 days of the change, there is no mention of when (or if) information must be submitted to the Agencies for re-review.

We therefore suggest that the Agencies provide more guidance on the factors they will consider in reviewing proposed ACOs.

## IV. Conclusion

Sutter Health respectively requests the Agencies to re-think the approach to the antitrust review of proposed ACOs. The current proposal creates substantial burdens and fails to achieve the goals of the Accountable Care Act's Medicare shared savings program for accountable care organizations.

Sincerely,

Florence L. Di Benedetto
Senior Vice President and General Counsel