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Federal Trade Commission
Office of the Secretary
Room H-113 (Annex W)
600 Pennsylvania Avenue, NW
Washington, DC 20580

United States Department of Justice
Antitrust Division
Office of the Assistant Attorney General
950 Pennsylvania Avenue, NW
Washington, DC 20530

RE: Proposed Statement of Antitrust Enforcement Policy Regarding ACO's Participating In the Medicare Shared Savings Program, Matter V1000017

Submitted via https:///ftcpublic.commentworks.com/ftc/acoenforcementpolicy.

Dear Sir or Madam:

We appreciate the Agencies' efforts to balance the positive public policy goals of ACO's development (facilitating the provision of more integrated, quality health care to America's seniors) with the need to avoid unintended consequences. We offer the following comments to help meet those twin objectives.

1. The Agencies should consider whether the definition of Primary Service Area could result in confusion and/or unintended consequences, especially if applied to the commercial market.

The Proposed Statement defines a participant's PSA as the lowest number of contiguous postal zip codes from which the ACO's participant draws at least 75 percent of its patients for that service (as measured on the basis of total allowed charges for all Medicare beneficiaries). This benchmark is not a traditional method of analyzing antitrust markets and could result in unintended consequences. For instance, the proposed methodology may create the potential for extreme fluctuation in PSA shares over a short period of time due to factors other than competitive influences such as the demographics or health status of the Medicare beneficiary population.

More importantly, it is unclear whether or how this formulation will be applied to an ACO's commercial operations. Do the Agencies intend to use the same PSA for an ACO participant's commercial operations as applies to the ACO participant's Medicare operations? If so, such an approach could give rise to inappropriate results based on an ACO participant's mix of Medicare and commercial patients (e.g., the provider may have a relatively small share of Medicare patients but large share of commercial patients in a given area, thus possibly resulting in a misleading antitrust analysis with respect to commercial patients). Or, rather, will the Agencies' attempt to calculate a separate PSA for commercial business (i.e., an area where the ACO participant draws at least 75% of its commercial revenues for a particular service)?

If so, how will the Agencies and private participants readily assess potential antitrust risk given the lack of publicly available relevant data? The Agencies' safety zone parameters or approval of a mandatory-review ACO, or CMS's acceptance of an ACO into the Medicare Shared Savings Program (SSP) based on these standards, may adversely impact other affected parties' ability to challenge adverse effects from the ACO under federal or state antitrust laws. Accordingly, the problematic method adopted in the Proposed Statement should be changed.

Recommendations: The Agencies should eliminate the PSA methodology and instead base its screens on more traditional antitrust market definitions.

2. The Agencies should independently determine whether a large/dominant ACO is sufficiently clinically and/or financially integrated to be subject to Rule of Reason analysis for its non-Medicare commercial market operations.

The Proposed Statement and corresponding CMS proposed regulations create a mandatory antitrust review for any ACO with a greater than 50 percent share of any common service in a PSA prior to participation in the SSP. The Agencies should also make an independent decision whether such ACO's will be examined using the Rule of Reason based on clinical or financial integration for the commercial market. As currently proposed, the Proposed Statement essentially cedes to CMS - whose responsibilities focus on the Medicare program - unfettered discretion to make the potentially dispositive decisions regarding antitrust enforcement matters critical to competition in commercial markets. The Agencies should retain independent discretion to address this issue in any determination made regarding an ACO's operations in the commercial markets.

Recommendation: The Agencies should retain discretion to make an independent determination of whether an ACO is sufficiently clinically or financially integrated to justify Rule of Reason treatment for its non-Medicare commercial market operations.

3. The Agencies should take steps to ensure that the pro-competitive characteristics leading to the issuance of a 'no action' letter remain intact for the duration of the ACO's participation in the SSP.

While the CMS proposed regulations require that an ACO that experiences a significant change in provider composition bringing it above the 50 percent PSA share threshold, or material changes from what was initially reviewed by one of the Agencies, must seek additional antitrust review, it is unclear what constitutes a 'material change' or whether the ACO may inherently become anticompetitive without any such 'material change', for example through the addition of one or several providers to an existing medical group.

Recommendation: The Agencies should take steps to ensure that the pro-competitive characteristics leading to the issuance of a 'no action' letter remain intact for the duration of the ACO's participation in the SSP.

4. The Agencies should further clarify the administrative procedural requirements and protections applicable to the mandatory review process.

The Proposed Statement sets out the informational requirements that ACO's must provide in order to receive expedited review for the mandatory review process. However, the Agencies do not address any other procedural processes, protections or expectations that apply for the ACO itself, its participants or third parties with whom the Agencies may consult during its review. For instance, what confidentiality protections apply to this process, both for ACO's/ACO participants and any third parties that may be consulted during the review? Will affected third parties, such as commercial payers, have any rights to participate in these proceedings where approval of ACO's will influence their ability to exercise market power in commercial markets? These procedural matters should be addressed in more detail and rights afforded third parties.

Recommendation: The Agencies should provide details of the administrative and procedural processes available to third parties to protect the confidentiality of their information, participate in the review process, and seek review of decisions adversely affecting them.

We believe that these clarifications and amendments will help ensure that ACO's are able to realize in practice their potential benefits in helping health care become more integrated, connected and aligned, but all within the context of active consumer choice and pro-competitive markets.

Thank you for the opportunity to comment.

Sincerely,

Gail K. Boudreaux