American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

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May 31, 2011

Donald S. Clark
Secretary
US Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Sharis A. Pozen
Chief of Staff
Office of the Assistant Attorney General
US Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

RE: Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program

Dear Mr. Clark and Ms. Pozen:

The American Academy of Pediatrics (AAP), a non-profit professional organization of 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, appreciates this opportunity to comment on the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (the Policy Statement) promulgated by the Federal Trade Commission (FTC) and the Department of Justice (DOJ) (collectively, the Antitrust Agencies). Unfortunately, the lack of clarity in the Policy Statement regarding the place of pediatric ACOs in the proposed antitrust "safety zone" creates disruptive incentives for commercial market actors that will make it harder for children to reap the quality improvement and cost savings promised by the Accountable Care Organization (ACO) model.

This lack of clarity regarding the safety zone also establishes an incentive for commercial market ACOs to exclude pediatricians and obstetricians/gynecologists as well. The Policy Statement encourages commercial market ACOs to rely on the Medicare database to conduct ACO safety zone analyses, thereby leaving commercial ACOs with no established options to evaluate whether the Antitrust Agencies will bring an enforcement action against them if they include pediatricians. This policy choice will serve as a strong signal to commercial market ACOs to exclude children and pregnant women, further fragmenting and disrupting the market.

Children and pregnant women deserve the opportunity to benefit from the quality and care coordination that ACOs hold the promise to improve. Indeed, section 3022 is not the only ACO model contained in the Affordable Care Act (ACA). Section 2706 authorizes HHS to establish Pediatric ACO Demonstration Projects. States participating in these demonstration projects must also depend on an antitrust analysis, but the Policy Statement offers no guidance.

We urge the FTC and DOJ to provide further guidance, create a structure for comparable antitrust review for ACOs that include children, and utilize an acceptable database of pediatric providers so that commercial ACOs will enjoy the relative certainty that they will survive the analysis of the Antitrust Agencies. Commercial and Pediatric ACOs must not be discouraged from including children and pregnant women due to an antitrust policy that ignores insurance beyond Medicare.

Thank you for your continued commitment to strengthening and improving high quality and efficient health care for children – whose families are consumers of health services as well. The Academy greatly appreciates the opportunity to collaborate to best implement the Affordable Care Act and we pledge to work with you to ensure that the policies flowing from this important law best meet the needs of children and pediatricians.

Thank you for the opportunity to comment on the Policy Statement. If the AAP may be of any further assistance, please do not hesitate to contact Robert Hall in our Washington, D.C. office at 202/347-8600 or rhall@aap.org. We look forward to future collaborations as you continue implementation of the Policy Statement and other regulations to improve the care of children under the Affordable Care Act.

Sincerely,

O. Marion Burton
President

OMB: rh

The American Academy of Pediatrics (the Academy) appreciates the opportunity to comment on the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (the Policy Statement) promulgated by the Federal Trade Commission (FTC) and the Department of Justice (DOJ) (collectively, the Antitrust Agencies). Unfortunately, the Policy Statement, unless modified, has the potential to harm children by excluding them from the proposed antitrust "safety zone." In addition, section 2706 of the Affordable Care Act (ACA), which establishes a model for a Pediatric ACO Demonstration Project, is mentioned only in passing. Guidance applicable to this section of the law would also help provide comfort for children to benefit from Pediatric ACOs and assurance for organizations and individuals that intend to develop or participate in a Pediatric ACO.

Without further information regarding these components of the Policy Statement, the policies set forth in the Policy Statement have the potential to harm children by excluding them from integrated care structures. We urge the Antitrust Agencies to either redraft the Policy Statement or issue new guidance that better addresses the unique needs of children.

Children and System Reform

Initially, it should be noted that fragmented care structures harm patients, including children. In its landmark To Err is Human Report, the Institute of Medicine established that close to 100,000 people die each year due to medical errors. The recent launch of the Partnership for Patients, which the Academy joined and strongly supports, and Center for Medicare and Medicaid Innovation, recognize that quality improvement should be a goal of all actors in the health system and that one of the successful ways to improve quality is through integrated care models. Pediatricians are quite familiar with these models, as pediatricians and families of children with special health care needs pioneered the medical home concept, coining the phrase in the 1960s, and evolving its application over the ensuing decades. More recently, the Academy helped establish the Patient Centered Primary Care Collaborative, and effectively advocated for the transformational quality improvement structures contained in Title IV of the Children's Health Insurance Program Reauthorization Act, which provides more than $200 million in funding over five years for pediatric quality measure development.

The Academy is firmly committed to quality measure development, system redesign and integrated care systems, but pediatricians often find themselves challenged to fund such improvements due to the fact that care for children is inexpensive, and thus not the current focus of the health care reform cost containment? efforts. Medicaid is the most important government finance mechanism for children's health, as more than half of all Medicaid enrollees are children. Unfortunately for cross-border system integration, Medicaid is a federal/state partnership, which creates opportunity for innovation at the state level, but can create more challenges in achieving a more coordinated approach than a federal program like Medicare. When policymakers view US health policy through the lens of the Medicare program, the results of this bias are not often positive for children. For example, pediatricians were excluded from the original e-prescribing incentives in Medicare and largely unable to secure HITECH Act funding for health information technology systems, because few pediatricians meet the statutory 20% threshold for the HIT incentive. Clearly, when Medicare is the focus of policy, it is much harder to address the unique health needs of children, even though the future costs of the health care system could be

effectively arrested by improving the health of the pediatric population. The behaviors and conditions that lead to today's pediatric overweight and obesity create tomorrow's diabetes, heart disease and cancer.

ACOs in the ACA

The Affordable Care Act (ACA) invests heavily in the future US health system. One such statutory policy is the Medicare Shared Savings Program (Section 3022). This section of the Act establishes Accountable Care Organizations as well as statutory standards for the program. A similar section of the ACA, Section 2706, sets forth standards for Pediatric ACOs. Despite this, the Policy Statement focuses almost exclusively on Section 3022. The Academy requests whether future guidance on pediatric ACOs will be forthcoming or, because Section 2706 currently is not funded, the Antitrust Agencies intend to allow the current Policy Statement to apply.

If the choice is the latter, it is difficult to discern how the Policy Statement could provide guidance for pediatric inclusion in a commercial ACO or a Pediatric ACO. The Policy Statement describes (l) the Accountable Care Organizations (ACOs) to which the Policy Statement will apply; (2) when the Agencies will apply rule of reason treatment to those ACOs; (3) an antitrust safety zone; (4) the Agency review of ACOs exceeding a 50 percent share threshold mandated by CMS under the Shared Savings Program; and (5) options for ACOs to obtain additional antitrust certainty if they are outside the safety zone and below the mandatory review threshold. It appears that the Antitrust Agencies have not considered the unique needs of children in crafting this Poliy Statement, even though children are close to one-third of the population.

Indeed, the Policy Statement sets forth multiple structures that may incentive commercial markets to make it harder to bring children the promise of coordinated care. For instance, in one case, the Policy Statement includes the following,

> Therefore, the Agencies will provide rule of reason treatment to an ACO if, in the commercial market, the ACO uses the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for and participate in the Shared Savings Program. This rule of reason treatment will apply to the ACO for the duration of its participation in the Shared Savings Program.

PSA Analysis

Commercial market ACOs do not receive clear guidance under the Policy Statement to determine whether the pediatric primary care or subspecialty physicians that may wish to engage in the ACO will do so in compliance with the antitrust laws as viewed by the Antitrust Agencies. To fall within an antitrust "safety zone," an ACO "must have a combined share of 30% or less of each common service in each participant's [Provider Service Area] (PSA), wherever two or more ACO participants provide that service to patients from that PSA."

The Antitrust Agencies will define the PSA for each service as ''the lowest number of contiguous postal zip codes from which the [ACO participant] draws at least 75% of its [patients]'' for that service. According to the Domestic Provider limitation, an ACO participant with a greater than 50% share in its PSA for any service that no other ACO participant provides

to patients in a PSA, must be non-exclusive to the ACO to fall within the safety zone. In addition, to fall within the safety zone, an ACO with a dominant provider cannot require a commercial payer to contract exclusively with the ACO or otherwise restrict a commercial payer's ability to contract or deal with other ACOs or provider networks. The Antitrust Agencies will set more stringent review standards for ACOs that have a share of 50% or higher for any common service that two or more independent ACO participants provide to patients in the same PSA.

Due to this policy, an ACO may have difficulty fitting into the safety zone if it includes children or pregnant women because the definition of a market and the pediatrician's place in that market may be unobtainable with certainty. The Policy Statement recognizes this issue to some degree but provides less than clear guidance, requiring information on whether a physician at issue is "actively participating" in the market.[1] It is unclear how the Antitrust Agencies will make that determination, and thus, come to a conclusion regarding whether the safety zone can be reached. This lack of certainty provides a real disincentive in the commercial market for ACOs to include pediatric primary care, even though ACOs are essentially medical homes writ large.

The Policy Statement requests comment regarding how a rigorous antitrust analysis may be conducted in the context of pediatrics. However, the Antitrust Agencies offer no realistic option for a safe harbor to protect ACOs that include pediatrics and/or obstetrics/gynecology because these physicians are not listed in the Medicare database. At one of the ACO events hosted by the FTC, FTC staff asked a panel whether it would be appropriate to use Medicaid to help define appropriate markets for antitrust analysis. In the Academy's experience, this proxy for the Medicare database would be highly problematic as some pediatricians do not serve a large proportion of Medicaid in their practices. AAP surveys report that the average pediatrician serves around 30% Medicaid in his or her average case mix, but that a significant number of pediatricians find Medicaid payment so low as to justify not participating in the program. Pediatricians are familiar with the concept of a "catchment area," but this too would be an inappropriate proxy as it is unclear whether this concept or other market analyses would appropriately identify the applicable market. The thrust of the Safety Zone analysis is to decrease ACO establishment transaction costs by creating an efficient way for an ACO applicant to gain some comfort that the proposed ACO satisfies appropriate antitrust hurdles in the view of the Antitrust Agencies. It appears that the Policy Statement does not contemplate providing this efficient analysis for ACOs that include pediatricians or Pediatric ACOs.

Compounding this problem, on page 4 of the Policy Statement, the Antitrust Agencies state,

> "if a CMS-approved ACO provides the same or essentially the same services in the commercial market, the Agencies have determined that the integration criteria are sufficiently rigorous that joint negotiations with private-sector

[1] See Page 13 of the Policy Statement, "For those services that are rarely used by Medicare beneficiaries (e.g., pediatrics, obstetrics, and neonatal care), the ACO may use other available data to determine the relevant shares. For example, for services where Medicare data are not applicable, data on the number of **actively participating physicians** within the specialty and within the PSA may be a reasonable alternative for the purposes of calculating shares of physician services." [emphasis added]

payers will be treated as subordinate and reasonably related to the ACO's primary purpose of improving health care services."

While designed to be pro-competitive, this policy injects uncertainty into the commercial market in the context of non-Medicare providers and creates a disincentive to include non-Medicare physicians as part of the ACO. Pediatrics is clearly primary care, yet by excluding primary care pediatricians from this antitrust analysis, the purpose of section 3022 of the Affordable Care Act is thwarted. Indeed, without an adequate understanding of antitrust analysis in the context of pediatrics in ACOs, section 2706 of the ACA will almost certainly lack pediatricians to participate.

Thank you very much for the opportunity to comment on the Policy Statement.