Patient First®

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Federal Trade Commission
Office of the Secretary
Room H-113 (Annex W)
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Re: Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program, Matter V100017

Dear Sir or Madam:

Thank you for the opportunity to provide information and comments in connection with the Proposed Statement of Antitrust Enforcement Policy (the "Statement") Regarding ACOs Participating in the Medicare Shared Savings Program under Section 3022 of the Patient Protection and Affordable Care Act (the "Act"). The Statement describes proposed enforcement policies of the Federal Trade Commission and Department of Justice with respect to the application of antitrust laws to providers and suppliers participating in accountable care organizations pursuant to a proposed rule promulgated by the Centers for Medicare and Medicaid Services and published in the Federal Register on April 7, 2011 (the "Proposed Rule"). As a growing primary and urgent care service provider with over 30 locations in Maryland, Pennsylvania and Virginia, Patient First Corporation ("Patient First") appreciates the opportunity to offer its perspective on the Statement, specifically, and more generally on the Proposed Rule, the Medicare Shared Savings Program (the "Program") and accountable care organizations.

I. Comments regarding the Statement.

Patient First is fully supportive of the care coordination, quality improvement and cost reduction goals of the Medicare Shared Savings Program and of the concept of accountable care organizations ("ACOs"). We commend CMS, DOJ/FTC and the HHS OIG (the "Agencies") for their coordinated approach to the proposed regulations. The Agencies' Statement has generated and will continue to generate constructive debate and comments from a significant portion of health care providers and we appreciate the opportunity to bring our experience to the discussion.

Patient First's perspective is that of a popular and growing operator of primary care/ urgent care centers in three states. For more than 25 years, we have seen competition and innovation produce patient-centered advances in ambulatory care -- in convenience and

in quality -- with costs well under control. We believe the Statement and the Proposed Rule miss the mark in certain areas. And we respectfully suggest in this letter how these proposals can be improved to better achieve their announced goals.

You will see below our comments specific to the Proposed Rule, which will be submitted to CMS, with minor modifications, by June 6. Please refer to those comments for factual background and marketplace analysis. Patient First's comments from an antitrust law perspective are as follows:

1. Care coordination, quality improvement and cost reduction can be best achieved by hospital and physician participation on a non-exclusive basis. Patient First is an "open market" physician group. There is no public benefit in requiring that primary care physicians participate in only one ACO. Further, we see no public benefit in allowing any physician or hospital to be prohibited from being a participant in multiple ACOs. At this stage, nearly all providers are investing in electronic medical records ("EMRs") and participating in various efforts to use clinical treatment protocols and adopt quality improvement measures. These providers are moving ahead with investment in EMR and adoption of interoperable systems in response to comprehensive incentives enacted under the Health Information Technology for Economic and Clinical Health Act provisions of the American Reinvestment and Recovery Act of 2009 ("HITECH"). HITECH includes both federal standards governing the interoperability of EMRs and the Medicare and Medicaid Electronic Health Record Incentive Programs to drive adoption by health care providers and suppliers. This is the wrong time to risk stifling improvement and innovation by allowing restrictions on competition that are not necessary for widespread adoption of EMRs and the attendant gains in quality improvement.

2. Non-exclusive participation in health care joint ventures has been the long-standing expressed preference of DOJ/FTC. ACOs involve inherent risks of market domination that call for reaffirmation of, not retreat from, your policy of non-exclusive participation as protection against harm to healthy competition.

3. As an "open market" physician group that provides primary and urgent care on a non-appointment and extended hours basis every day of the year, Patient First is a community resource. We have over 25 years of experience using our own EMR system, enhanced by more recent modules such as e-prescribing. As all providers gain access to EMRs, the opportunities for professional coordination of care are enormous. And those opportunities need to be able to develop in a free and open market. Innovation in care coordination and cost reduction is impeded by provider exclusivity. Patients are gaining more and more access to relevant information and must be free to use that information to select the providers that best meet their service and cost needs.

4. Your safe harbor measures of market power can be relaxed and rendered more effective by encouraging non-exclusive ACO participation at this very early stage

of ACO development. All providers are interested in exploring ACO participation at some level. In any form, ACO participation requires a substantial commitment of professional and administrative effort to meet the ACOs contractual obligations. EMRs, enhanced patient communication, compliance with clinical treatment protocols, reporting of quality measures and other basic aspects of ACO represent substantial financial and time commitments. There is no such thing as an ACO "free rider." A non-compliant ACO participant will be terminated by the ACO. Sharing of losses by an ACO, in the third year or all three years, is not necessary as an indication of shared financial commitment at this stage and will, in fact, deter participation at this early stage of development. ACO participation by contract is sufficient.

II. Comments regarding the Proposed Rule.

Background. Patient First provides medical services to patients at 34 medical centers located in Maryland, Pennsylvania and Virginia. Patient First's patients include Medicare (FFS and Medicare Advantage), Medicaid managed care, Tricare beneficiaries, patients with commercial insurance, and self-pay patients. Patient First medical centers are open from 8 a.m. to 10 p.m. 365 days a year and provide on-site physician and physician extender (physician assistant and nurse practitioner) services, digital x-ray, CLIA-certified laboratory and prescription dispensing services, all on a non-appointment basis.

Patient First provides traditional primary care as well as urgent care services on a non-appointment basis, both with extended hours. Almost 30% of Patient First's patients use a Patient First physician as their primary care physician, and Patient First is the largest provider of primary care in Virginia.

Patient First's employed physicians, like those employed by most urgent care providers, are "primary care physicians" by definition under the Proposed Rule.

Patient First's Role in the Continuum of Care. Commentary to the Proposed Rule focuses, in substantial part, on avoidance of costly hospital emergency room visits . Patient First is well situated to serve this goal in two ways.

First, Patient First offers timely access. Patient First centers are open from 8 a.m. to 10 p.m. every day of the year and operate on a non-appointment basis. With this schedule, Patient First centers are open 98 hours a week, compared to typical doctors' office hours of 40 hour a week. For many patients, the choice for primary or urgent care on weekday evenings, weekends and holidays is between a Patient First center and a hospital emergency room.

Second, Patient First offers these services at a substantially reduced cost. Patient First physicians routinely care for patients whose diagnoses represent over 70% of hospital emergency department patient visits. In the 12 month period ending April 30, 2011,

patients made 1,279,000 visits to Patient First. A substantial percentage of those patients would otherwise have visited the emergency room at significantly greater cost because they required care outside normal business hours, required care for urgent conditions, or lacked access to a traditional primary care physician. In 2008, the average reimbursement for services provided by Patient First was less than $150. In the same year, according to data published by the Maryland Health Services Cost Review Council, the average reimbursement for identical services provided in a hospital emergency department was over $612.

As a provider of both primary and urgent care (each with extended hours), Patient First is well situated to offer comments on the manner in which such services may be integrated into ACOs. We share the sense of the Act and CMS that the active participation of a range of health care providers is critical to the coordination and delivery of efficient, high quality health care services and the realization of savings for the Medicare program. Our experience demonstrates that providers of primary and urgent care with extended hours deliver exactly the kind of care that patients often seek from hospital emergency departments but at a fraction of the cost. The cost savings provided by offices like Patient First are so substantial that we view these services to be an indispensable component of any ACO.

In addition, like most urgent care providers, Patient First has always been an "open market" provider. We cooperate with all hospital and physician providers on a non-exclusive basis, as a resource open to all patients who may otherwise use the hospital emergency room for primary or urgent care. We have our own clinical treatment protocols and are able to adhere to the protocols established by any ACO. We routinely coordinate referrals and follow-up care with specialists for patients who require specialist services. We have had a comprehensive electronic medical records system in operation continuously for over 25 years. We, and others like us, have achieved wide popularity with insurers of all types, including government programs, and are now a well-established component of the continuum of care for all patients in the geographic areas we serve. Commercial payors incentivize and actively encourage their insureds to utilize Patient First rather than hospital emergency rooms.

We believe that fundamental changes are required in the Proposed Rule if CMS is to realize its goals of (i) encouraging a wide range of physicians to participate in the Program and make it a long-term success, (ii) ensuring that the Program promotes the development of multiple, competing ACOs in healthcare markets, resulting in downward pressure on costs through healthy competition, and (iii) ensuring that each ACO has access to the full range of providers and suppliers necessary to produce high quality medical care. We have identified two sets of options that would better facilitate these goals, together with a third feature that we believe should be included in any final rule, and offer comments on each, below.

A. Option One

Background: The Proposed Rule provides for the assignment of Medicare beneficiaries to an ACO based on such beneficiaries' utilization of primary care services provided by primary care physicians who are ACO participants. "Primary care physicians" are those with a primary specialty designation of internal medicine, general practice, family practice or geriatric medicine. "Primary care services" are defined as services provided by primary care physicians and identified by HCPCS "evaluation and management" codes 99201 through 99215.

As commentary to the Proposed Rule notes in several places, primary care physicians are critical to the Program's success at coordinating care in a manner that improves quality and outcomes while controlling costs. It is fair to say that, without the active and enthusiastic participation of a wide range of primary care physicians, an ACO cannot realize these goals.

Yet the Proposed Rule requires primary care physicians, and the practices that employ them, to limit their participation to a single ACO. Specifically, Section 425.5(c) of the Proposed Rule provides that "each ACO participant TIN upon which beneficiary assignment is dependent ... will be exclusive to one ACO." This requirement will discourage participation by primary care physicians and the practices that employ them for a number of reasons:

- Large primary care physician practices may not be willing to participate exclusively in an ACO due to existing referral patterns, patient preference, hospital relationships, concerns about patient care, or for competitive reasons.[1] Similarly, large physician practices with multiple offices may find that their patients are simply unwilling to accept new referral arrangements, resulting in "leakage" from the ACO and a reduction in savings.

- Moreover, a requirement that all individual primary care physicians in a group practice participate exclusively with an ACO would discourage primary care physicians from participating at all in markets that have multiple hospital systems. In such markets, primary care physicians (including urgent care providers like Patient First) may be reluctant to affiliate with a single system, because their patients use physicians who are affiliated with or employed by each of the competing hospital systems (and they stand to lose patients if they "choose a side"). For example, a primary care practice may have patients who have long-standing relationships with specialists in two different ACOs. Restricting such a practice to membership in a single ACO is likely to cause it to opt out of

[1] We recognize that the Proposed Rule does not formally require primary care ACO participants to refer within the ACO or restrict their ability to refer outside of the ACO. However, the Program is clearly intended to incentivize referrals to ACO participants who share treatment and quality protocols and to reduce referrals outside of the ACO network. Moreover, provider protocols adopted by ACOs themselves are likely to have strong incentives to refer within the ACO.

participation in any ACO at all rather than lose those of its patients who are unwilling to accept referral to a new specialist.

- In relatively smaller geographic markets, the exclusivity requirement may also hamper the development of multiple ACOs that will compete to provide the most efficient, highest quality care because the market might not contain a sufficient number of primary care physician group practices to populate multiple ACOs on an exclusive basis. While the principal goal of the Program is to control costs through the ACO model, if the ACO model encourages or requires the consolidation of primary care physicians into a single ACO competition within such a market will be reduced and cost reduction is unlikely to result beyond the very short term, even with shared losses. Additionally, if the final rule restricts or discourages the development of multiple ACOs within certain markets, CMS will be deprived of the ability to compare ACOs with relatively homogeneous populations for the purpose of evaluating the Program and developing other initiatives.

- In addition, a final rule that requires primary care physicians to participate as a group practice in a single ACO will discourage integrated multispecialty physician groups from participating. One commenter noted as much at the listening session sponsored by CMS on Thursday, May 12, 2011. Multispecialty physician practices typically include both primary care physicians and specialists. Due to their complement of primary care physicians, the Proposed Rule would require multispecialty practices to participate in a single ACO and would likely cause such groups to opt out of participation rather than risk causing their specialist physicians to lose referrals from third party primary care providers.

- Finally, the requirement that physician groups employing primary care physicians participate exclusively with a single ACO will have a substantial deterrent effect on urgent care providers, like Patient First, that would otherwise wish to participate in the program because, as noted, most urgent care physicians meet the definition of "primary care physician" under the Proposed Rule. Access to urgent care will be critical for any ACO that intends to realize savings by encouraging patients to receive services at the most appropriate site for their needs (e.g., an urgent care center rather than a hospital emergency room).

  For urgent care to function appropriately, it must have access to hospital emergency services for the small percentage of urgent care patients who require referral to the emergency department for additional treatment. Urgent care providers typically work closely with local hospital emergency departments to secure prompt emergency care for such patients, and urgent care providers with multiple locations (like Patient First) may refer to several different emergency departments and hospital systems in a single market. While the Proposed Rule does not formally require ACO participants to refer within the ACO, it is clearly a goal of the Program to encourage referrals among ACO participants (who will have common protocols designed to manage care efficiently and reduce costs) and

guidelines adopted by ACOs themselves are likely to have strong incentives to refer within the ACO. If the final rule restricts urgent care providers to a single ACO (and likely to a single hospital or hospital system as a result), whether formally or on a *de facto* basis, it will interfere with prompt emergency care and is likely to cause urgent care providers in a market that has more than one hospital system to decline participation.

Comment:

As commentary to the Proposed Rule notes repeatedly, active participation by primary care physicians is a crucial component to an ACO's ability to improve outcomes and reduce costs. Yet, for the reasons noted above, the Proposed Rule's requirement that primary care physicians participate exclusively with one ACO is likely to deter many primary care physicians, including urgent care providers, from participating in the Program. CMS should make every effort to avoid a final rule that drives, or has the potential to drive, primary care physicians from the Program.

CMS' decision to assign beneficiaries based on their provider of primary care physician services is the basis for the exclusivity requirement. There are other options available for assignment of beneficiaries, including assignment based on the totality of services (rather than primary care services alone). Indeed, it is reasonable to believe that assignment based on the totality of services more properly allocates risk to the ACO that is most responsible for the cost of a patient's care: it makes little sense to assign a patient to one ACO based on his or her relatively low cost primary care if the patient has received hospital care, at substantially higher cost, from a hospital affiliated with a different ACO.

We are not advocating a specific method for assignment of beneficiaries. However, we do advocate strongly that CMS develop an alternate system of assignment in order to encourage primary care physicians to participate in the Program and enhance its chance of success. The Proposed Rule will materially deter practices employing primary care physicians from participating in the Program at all, whether they are urgent care providers, integrated multispecialty groups, or simply stand alone primary care physician groups with multiple existing referral relationships.

In order to ensure that primary care physicians and their group practices participate fully in the Program, the final rule should (i) eliminate the requirement that primary care physicians participate exclusively in a single ACO, by (ii) allowing for the assignment of beneficiaries to ACOs on a basis other than such patients' primary care physician.[2]

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[2] Moreover, proper management of a patient's care by a primary care physician does not require the physician to participate exclusively in one ACO so long as beneficiaries are assigned prospectively. CMS has already indicated, in the Request for Applications to participate in the Pioneer ACO Model issued on May 19, 2011, that it will use a program of prospective identification and alignment of beneficiaries with Pioneer ACOs. If patients are assigned prospectively and the primary care physician is intended to be the "manager," this function can be accomplished by coordinating care according to protocols developed by ACOs. Such activity does not have to be on an exclusive basis to be effective.

their status as "open market" providers who offer cost-effective urgent care to all patients, regardless of the patients' ACO affiliation. However, if urgent care physicians' evaluation and management services are considered for purposes of beneficiary attribution, local ACOs will actively discourage their participants from referring patients to the more efficient, lower cost urgent centers for fear of losing assigned beneficiaries.[4] Even if urgent care providers agree to participate in an ACO, a final rule that restricts such providers, as "primary care physicians," to a single ACO will have the effect of denying competing ACOs access to urgent care services (because they will not wish to lose beneficiaries), detracting materially from their ability to lower emergency department costs, and will eventually reduce the number of ACOs competing in a given market.

If CMS insists on a system of retroactive beneficiary assignment, the final rule must permit urgent care providers and other "primary care physicians" to elect to be treated as "specialists" whose services are not considered for purposes of beneficiary assignment and who are not required to be exclusive to one ACO. Otherwise, such providers will have a choice of either (i) declining to participate in any ACO, a result that will reduce the Program's effectiveness and increase duplication of services and costs in the local health care market, or (ii) participating in a single ACO in each market, to the detriment of other competing ACOs' efforts to reduce unnecessary emergency room costs and, more importantly, to the detriment of patients who would receive less efficient, higher cost care.

2. **Section 425.5(b) of the Proposed Rule requires ACO professionals to participate (i) through their group practice entities, (ii) in partnership or joint venture arrangements with hospitals, or (iii) as hospital employees. It is not clear that an ACO professional is permitted to participate with an ACO on an individual basis, even if other members of his or her group practice participate with a competing ACO or elect to remain independent. The final rule should state clearly that ACO professionals may elect to participate or not participate in an ACO on an individual basis, independent of the decisions made by other ACO professionals who are members of, or employed by, their practice entity.**

In order to achieve the Program's principal goal of generating shared savings, the final rule should focus on a flexible approach that will accommodate a wide range of ACO structures and participants. The Proposed Rule appears to prohibit a primary care physician group practice from participating in more than one ACO, and it certainly does so if the practice's patients will be used for beneficiary attribution purposes. For the multiple reasons discussed in Section I of this letter, a final rule that requires physician groups that employ multiple primary care physicians, or a mix of primary physicians and

[4] As previously noted, most urgent care physicians have a primary specialty that constitutes "primary care" under the Proposed Rule, so their evaluation and management services will be considered for assignment purposes regardless of whether they are ACO participants.

specialists, to participate exclusively in a single ACO will substantially reduce primary care participation in ACOs.

One avenue to encourage participation by a wide range of primary care physicians and group multispeciality practices would be to permit ACO professionals to elect to participate or not participate in an ACO on an individual basis, independent of the decisions made by other ACO professionals who are members of, or employed by, their practice entity. Under such a model, individual physicians in a primary care practice would be able to participate in different ACOs, thereby preserving existing referral patterns, reducing the likelihood of patient leakage, and promoting competition within a given market. Similarly, individual physicians, in particular specialists, in a multispecialty practice could participate in different ACOs (or elect not to participate), increasing the likelihood that such practices play a role in making the Program a success.

In addition, a final rule that permits physicians to make an individual decision to participate or decline to participate will encourage practices that employ primary care physicians and offer services in multiple geographic markets to participate in ACOs. For example, Patient First is the largest provider of primary and urgent care physician services in Virginia. Patient First physicians practice in four distinct geographic markets in the Commonwealth of Virginia but do so as a single group practice and as part of a single corporate entity. Hospital services are provided by a different mix of local and regional health systems in each of our four Virginia markets and we foresee the development of different ACOs in each market. The Proposed Rule requires ACO participants that consist of primary care physician group practices to participate exclusively in a single ACO. Under the Proposed Rule, Patient First – a substantial provider of primary and urgent care services in Virginia - will not be able to participate in an ACO in three of its four markets, which will reduce the number of primary care physicians available to the Program in three of the four largest markets in Virginia. If individual physicians are able to elect to participate, this impediment no longer exists.

C. General Comment

One clear goal of the Program is to encourage the development of ACOs in multiple formats, so long as they are capable of coordinating care among multiple providers in a manner that reduces costs while increasing the quality of care. We believe that it is critical to the success of the Program for the final rule to offer maximum flexibility in the design of ACOs and the interaction of providers and suppliers who offer services to ACO beneficiaries

Comment:

For reasons discussed above, certain providers in a given market may be unable or unwilling to participate as members in an ACO. In order to maximize the number of professionals who agree to work collaboratively to achieve savings for the Medicare program, the final rule should (i) clearly permit ACOs to arrange for medical services

using contracted providers and suppliers who are not ACO participants, and (ii) permit the distribution of shared savings and/or allocation of losses to such providers and suppliers via contract. At a minimum, the final rule should clearly permit contract providers and suppliers to share data with ACOs and participate in clinical treatment protocols and quality performance, improvement and reporting initiatives even if they are not eligible to share in savings and losses under the Program.

There may be a number of business reasons that primary care physicians, specialists and sub-specialists decline to participate formally as ACO professionals, but the services offered by such physicians will remain critical components of the efficient and coordinated care offered by ACOs. The final rule should permit ACOs to secure necessary medical services via contract in order to ensure that each ACO is able to offer the entire continuum of care and encourage its patients to receive care in the most efficient, appropriate site of service.

Moreover, Section 3022(f) of the Act provides the Secretary with the authority to waive "such requirements of sections 1128A and 1128B and title XVIII of [the Social Security Act] as may be necessary" to foster the development of ACOs under the Program. The Secretary should use her authority to promulgate appropriate safe harbors and exceptions under the Medicare/Medicaid Anti-Kickback Statute, 42 U.S.C. §1320a-7b, and the Physician Self-Referral Law, or Stark, 42 U.S.C. §1395nn, respectively, to permit ACOs to secure physician services, including urgent care services, and to distribute shared savings and allocate losses by contract.

We appreciate the opportunity to comment on the Statement and the Proposed Rule and look forward to working with both the Agencies and CMS during the final rulemaking and implementation phases of the Program. Please feel free to contact me at (804) 822-4550 with questions or if you would like additional information. Thank you.

Sincerely,

R.P. Sowers, III, M.D.
Chairman and Chief Executive Officer